* NOTICES *

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CLAIMS

[Claim(s)]
[Claim 1]A blood pump device which can carry out the implant to a patient in order to supply blood to a patient's circulatory system characterized by comprising the following.
a. Pump housing which has a drive chamber.
b. A base part combined with pump housing.
c. A compressive blood chamber which has a flank which adjoins a base part and has an entrance and an exit which can be combined with the circulatory system, respectively.
d. A movable plate which adjoins a base part of a blood chamber at a flank of an opposite hand, and e. The 1st end combined with a movable plate enabling free pivot motion

[Claim 2]Drive mechanism is a. An eccentric shaft and b. By an end of an eccentric shaft, the 2nd movable end of an arm, c. When it is made a motor stored in a drive chamber, it has the output shaft combined with an end which faces this motor of an eccentric shaft and an output shaft rotates an eccentric shaft, an arm carries out pivot motion and by that cause, A blood pump device of Claim 1 which contains further a motor by which a movable plate carries out pumping of the blood through the circulatory system.
[Claim 3]A blood pump device of Claim 2 which the 2nd end of an arm contacts the circumference of an end of an eccentric shaft, and an eccentric shaft drives an arm in pumping distance, and does not restrain movement of an arm in a backward stroke.
[Claim 4]A blood pump device of Claim 3 with which a roll bearing attached to an end of an eccentric shaft mediates the 2nd end and eccentric shaft of an arm, and an arm contacts a roll bearing.
[Claim 5]A blood pump device of Claim 2 which contains further a reduction gear combined with the mid-position of an output shaft of a motor, and an end of an eccentric shaft.
[Claim 6]A blood pump device of Claim 5 with which a reduction gear contains a planetary-

gear-type reduction gear.
[Claim 7]A blood pump device of Claim 6 with which a planetary-gear-type reduction gear contains a reduction gear of 3 gear differential form.
[Claim 8]A blood pump device of Claim 7 with which a planetary-gear-type reduction gear contains internal flywheel starter gear further.
[Claim 9]A blood pump device of Claim 8 with which a planetary-gear-type reduction gear contains four planetary gears.
[Claim 10]A blood pump device of Claim 2 which attached an arm to a flat surface which intersects perpendicularly with axis of rotation of an eccentric shaft.
[Claim 11]A blood pump device of Claim 1 which detects a position change of an arm and with which a position sensing device for [of blood volume in a blood chamber and an eccentric shaft position] determining at least any they are is arranged in a drive chamber.
[Claim 12]A blood pump device of Claim 11 with which a position sensing device is allocated in the mid-position of an arm by adjoining each other in order to detect an angle variation of an arm.
[Claim 13]A blood pump device of Claim 12 with which a position sensing device contains an eddy current sensor.
[Claim 14]A blood pump device of Claim 1 which contains further a bellows member which prevents body fluid from invading into a drive chamber while the seal of the circumference of an end of a drive chamber and the 2nd end of an arm is carried out and pivot motion of an arm is permitted.
[Claim 15]A blood pump device of Claim 12 with which the sealing seal of the bellows member is carried out.
[Claim 16]A blood pump device of Claim 1 which includes further an electronic control object in which implant for being combined with drive mechanism on an operation, and controlling drive mechanism is free.
[Claim 17]A blood pump device of Claim 1 which contains further an envelopment bag which makes it an envelopment bag which surrounds a blood pump device and has at least an opening of a blood chamber in which a seal for an entrance and an exit is free, and provides the surface which adapts itself to an organization and, in which an organization is made not to be involved in between movable parts of a blood pump device.
[Claim 18]It is a blood pump device of Claim 17 which can change freely so that an envelopment bag may not produce a pressure differential around an envelopment bag.
[Claim 19]A blood pump device of Claim 1 which contains further a compressive blood chamber which has the inner surface which gave a surface pattern to which a compressive blood chamber is used and a manifestation of biological intima lining is urged.
[Claim 20]A blood pump device which can carry out the implant to a patient in order to supply

blood to a patient's circulatory system characterized by comprising the following.
a. Pump housing which has a driving portion and pump parts.
b. A compressive blood chamber which makes it a compressive blood chamber allocated in pump parts, and has a freely connectable entrance and an exit respectively in the circulatory system.
c. At least one movable plate positioned by adjoining at least one blood chamber side in order to compress a blood chamber to a blood pump device.
d. The 1st end and omitted portion.

[Claim 21]A blood pump device of Claim 20 which the 2nd end of an arm contacts the circumference of an end of an eccentric shaft, and an eccentric shaft drives said arm in pumping distance, and restrains movement of an arm in a backward stroke.
[Claim 22]A blood pump device of Claim 21 which contains further a roll bearing attached to an end in contact with an arm of an eccentric shaft.
[Claim 23]A blood pump device of Claim 20 which contains further a reduction gear combined with the mid-position of an output shaft of a motor, and an end of an eccentric shaft furnished with this output shaft.
[Claim 24]A blood pump device of Claim 23 with which a reduction gear includes planetary-gear array constitution.
[Claim 25]A blood pump device of Claim 24 with which a planetary-gear-type reduction gear contains a reduction gear of 3 gear differential form.
[Claim 26]A blood pump device of Claim 25 with which a reduction gear contains inside flywheel starter gear further.
[Claim 27]A blood pump device of Claim 26 with which a planetary-gear-type reduction gear contains four planetary gears.
[Claim 28]A blood pump device of Claim 20 attached in a flat surface where axis of rotation of an eccentric shaft and an arm cross at right angles.
[Claim 29]A blood pump device of Claim 20 which contains further a position sensing device allocated in a drive chamber in order to detect a position change of an arm and to determine at least blood volume in a blood chamber, and one side of an eccentric shaft position.
[Claim 30]A blood pump device of Claim 29 which contains further a position sensing device which adjoins each other, is allocated in the mid-position of an arm, and detects an angle variation of an arm.
[Claim 31]A blood pump device of Claim 30 with which a position sensing device contains an eddy current sensor.
[Claim 32]A blood pump device of Claim 20 with which a lung moves with a movable plate on the occasion of blood pumping, and a part for capacity change of a blood pump device is

compensated by a lung by that cause when the implant of the blood pump device is carried out in the state of making at least some movable plates adjoining a part of lung.
[Claim 33]A blood pump device of Claim 30 which contains further a bellows member which prevents body fluid from invading into a drive chamber while it is made a bellows member which carries out the seal of the circumference of an end of a drive chamber, and the 2nd end of an arm and pivot motion of an arm is permitted.
[Claim 34]A blood pump device of Claim 33 with which the sealing seal of the bellows member is carried out.
[Claim 35]A blood pump device of Claim 20 which includes further an electronic control object in which implant for being combined with drive mechanism on an operation, and controlling drive mechanism is free.
[Claim 36]A blood pump device of Claim 20 which contains further an envelopment bag which makes it an envelopment bag which surrounds a blood pump device and has at least an opening of a blood chamber in which a seal for an entrance and an exit is free, and provides the surface which adapts itself to an organization and, in which an organization is made not to be involved in between movable parts of a blood pump device.
[Claim 37]It is a blood pump device of Claim 36 which can change freely so that an envelopment bag may not produce a pressure differential around this envelopment bag.
[Claim 38]A blood pump device of Claim 20 which contains further a compressive blood chamber which has the inner surface which gave a surface pattern for using a compressive blood chamber and urging a manifestation of biological intima lining.
[Claim 39]In order to supply blood to a patient's circulatory system, it is a blood pump device which can carry out the implant to a patient, and it is a. Pump housing which has a driving portion and pump parts, b. A compressive blood chamber which makes it a compressive blood chamber allocated in pump parts, and has a freely connectable entrance and an exit respectively in the circulatory system, c. At least one movable plate positioned by adjoining at least one blood chamber side in order to compress a blood chamber to a blood pump device, d. Make it at least one arm which has the 1st end and omitted portion, An arm by which said 1st end is combined with a movable plate, enabling free pivot motion, and an omitted portion is combined with pump housing enabling free pivot motion, e. By making it drive mechanism which was stored in a drive chamber and combined with the 2nd end of an arm, and carrying out pivot motion of the arm a center [said omitted portion], Drive mechanism to which make a movable plate, a blood chamber is made to compress into, and pumping of the blood is carried out through the circulatory system, and f. The circumference of an end of a drive chamber and the 2nd end of an arm is used as a bellows member which carries out a seal, A bellows member which prevents body fluid from invading into a drive chamber while pivot motion of an arm is permitted, and an included blood pump device.

[Claim 40]A blood pump device of Claim 39 with which the sealing seal of the bellows member is carried out.
[Claim 41]Drive mechanism is a. An eccentric shaft and b. By an end of an eccentric shaft, the 2nd movable end of an arm, c. Make it a motor stored in a drive chamber, and it has the output shaft combined with a **** motor of an eccentric shaft, and a receiving end, A blood pump device of Claim 39 which contains further a motor by which an arm will carry out pivot motion if this output shaft rotates an eccentric shaft, and said movable plate carries out pumping of the blood through the circulatory system.
[Claim 42]A blood pump device of Claim 41 which the 2nd end of an arm contacts the circumference of an end of an eccentric shaft, and an eccentric shaft drives an arm in pumping distance, and does not restrain movement of an arm in a backward stroke.
[Claim 43]A blood pump device of Claim 42 which contains further a roll bearing which is attached to the mid-position of an end of an eccentric shaft, and the 2nd end of an arm, and contacts an arm.
[Claim 44]A blood pump device of Claim 41 which contains further a reduction gear united in the middle with an end which faces an output shaft of a motor, and this output shaft of an eccentric shaft.
[Claim 45]A blood pump device of Claim 44 with which a reduction gear includes planetary-gear array constitution.
[Claim 46]A blood pump device of Claim 45 with which a planetary-gear-type reduction gear contains a reduction gear of 3 gear differential form.
[Claim 47]A blood pump device of Claim 46 with which a reduction gear contains inside flywheel starter gear further.
[Claim 48]A blood pump device of Claim 47 with which a planetary-gear-type reduction gear contains four planetary gears.
[Claim 49]A blood pump device of Claim 41 attached in a flat surface where axis of rotation of an eccentric shaft and an arm cross at right angles.
[Claim 50]A blood pump device of Claim 39 which contains further a position sensing device allocated in a drive chamber in order to detect a position change of an arm and to determine either [at least] blood volume in a blood chamber, or a position of an eccentric shaft.
[Claim 51]A blood pump device of Claim 50 which contains further a position sensing device which adjoins each other, is allocated in the mid-position of an arm, and detects an angle variation of an arm.
[Claim 52]A blood pump device of Claim 51 with which a position sensing device contains an eddy current sensor.
[Claim 53]A blood pump device of Claim 39 which includes further an electronic control object in which implant for being combined with drive mechanism on an operation, and controlling

drive mechanism is free.
[Claim 54]surrounding a blood pump device -- and a blood chamber -- even if small, it is made an envelopment bag which has an opening in which a seal for an entrance and an exit is free, and the surface which adapts itself to an organization is provided, and an organization is not involved in between movable parts of a blood pump device -- making -- a blood pump device of Claim 39 which contains an envelopment bag further.
[Claim 55]It is a blood pump device of Claim 54 which can change freely so that an envelopment bag may not produce a pressure differential around this envelopment bag.
[Claim 56]A blood pump device of Claim 39 which contains further a compressive blood chamber which has the inner surface which gave a surface pattern for using a compressive blood chamber and urging a manifestation of biological intima lining.
[Claim 57]A method characterized by comprising the following for supplying blood to a patient's circulatory system.
a. A blood chamber.
The implant of the blood pump device of a good change product which has at least one outer surface where it moves according to capacity change of this blood chamber is carried out to a patient, b. Said at least a part of at least one outer surface is made to adjoin a part of lung, it is positioned so that a lung can move with this outer surface, and flexibility for a variable capacity blood pump device is provided.

[Claim 58]c. A position signal which displays a fullness situation of a blood chamber relative at least from a position sensing device linked to a blood pump device of a good change product and a situation of a relative sky is received, d. A method for supplying blood to the circulatory system of a patient of Claim 57 which includes further answering said position signal which displays a relative fullness situation of a blood chamber, and starting a pumping action.
[Claim 59]A reference signal which indicates that it is in a situation where a situation of a blood chamber is preferred in order that a. blood chamber may start a pumping action is determined, b. Calculating a differential coefficient of the beginning of a position signal, and c. It detects that numerals of the first differential coefficient are negative, d. Answer detection of such negative numerals and compare a position signal with a reference signal, e. A method for supplying blood to the circulatory system of a patient of Claim 58 determined more without adjusting speed of a blood pump device of a good change product in proportion to a difference between a position signal and a reference signal, and making it equivalent [a position signal] to a reference signal on the whole.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention]Generally this invention relates to the detailed single-chamber blood pump device in which the perfect implant is possible about the blood pump device in which the implant is possible.
[0002]
[Description of the Prior Art]A seriously injured cardiac insufficiency condition, i.e., the condition to which it becomes impossible for the heart to send sufficient blood which the body needs, produces a remarkable fall and the immense health care cost of a living standard, and tens of thousands of person dead per year. In order [this] to cope with it sick, pharmacology and many biological intervention measures (those many are patents) like a device were devised, but cardiac insufficiency is main problems of public health as usual in spite of such efforts.
[0003]Cardiac insufficiency is judged because the amount of heart blood **** or the cardiac index is unusually small. The amount of heart blood **** (it is also hereafter called CO) is measured by the blood liter flow per per minute, and calculates the cardiac index (it is also hereafter called CI) as a value which **(ed) the CO value with the patient's surface area of a body (it is also hereafter called BSA). Usually, CI values are 3.0-3.5 during the time of a rest in the daytime, or activity. By a male, by per minute 5.6-6.5 l. and a woman, since a CO value has little surface area of a body, it turns into values a little fewer than it. The CI value of seriously injured cardiac insufficiency is a case of 1.5 to 2.0. In the case of a certain man's average cardiac insufficiency patient whose CO value is per minute 3.27 and whose surface area of a body is 1.87m^2, the blood volume to which the heart rate (it is also hereafter called BPM) of 1.75 and per minute is sent out for a CI value with 80 or 1 beat is an average of 41 ml. This average heartbeat blood volume is conspicuous when CI contrasts with 76 ml whose 3.25

and BPM(s) are the average heartbeat blood volume of the usual male of 80, and there is.
[little]
[0004]There are an inlet valve (mitral valve) and an outlet valve (aortic valve) in the main-process-pump room or left ventricle (it is also hereafter called LV) of the heart. Since an inlet valve is closed while the left ventricle contracts, blood is extruded through an outlet valve and goes into a main artery. Diastolic blood pressure of the left ventricle Although it is 2 - 20mmHg (it is also hereafter called preload), while having caused cardiac insufficiency, it becomes a value with this higher range. Typically, the left ventricle must resist the aortic pressure which is 70 - 140mmHg (it is also hereafter called an after load), and must discharge blood at the contraction stage. If an after load falls by cardiac insufficiency, heartbeat blood volume increases automatically. This is the Reason a cardiac insufficiency patient is saved with after load fall medicine like ACE depressant.
[0005]There are some which use an opposite pulsation device (it is also hereafter called IABS), for example, an arterial pump, in the general approach which provides a mechanical circulation auxiliary. IABS provides the circulation auxiliary in after load fall form, and is typically used for short-term use (namely, several hours to day). The main benefit of such a device is brought about by making a systole release the left ventricle from load, and increasing the cardiac dilatation pressure for the reperfusion of a coronary artery and the other arteries of a diastole by that cause so that it may be indicated to US,4,733,652,B and 3,692,018, respectively. The patient who needs the treatment of this form is afflicted by the cardiogenic shock and the chronic angina, or the circulation support (Kormos1987 in 1988 besides Nanas) under operation is needed. IABA design shape arranges the bulky balloon drive unit which needs to be stored on the bed of a hospital to a patient's outside of the body.
The use is limited only to an acute use.

[0006]The porch type auxiliary ventricle which has the mechanical means or pneumatic pressure means for carrying out pumping of the stored blood is indicated to US,3,553,736,B and 4,034,742, respectively. Many of both such the auxiliary ventricles have a single access port which provides the entrance and exit for a blood flow. There is a disadvantage that stagnation of a relative flow increases the danger of clot-of-blood formation or the thromboembolism in such design shape. Parallel connection of the auxiliary ventricle of others which have each port of an entrance and an exit both can be carried out to an artery. It may have the valve which meant that the thing of such design shape maximized pumping efficiency (US,4,195,623,B and 4,245,622).
[0007]"a dynamical artery patch" indicated to US,4,630,596,B and 4,051,840 is what is everlastingly attached to an artery -- opposite pulsation -- it has the design shape which provides legal cardioassist. Since this device means long-term use, in order to incorporate this,

it needs to cut a patient's thorax open. Like IABP, this device unit is arranged to a patient's outside of the body, and a patch expands by pneumatic pressure through an endermic access port. Unlike IABP, according to this dynamical artery patch, assistance by larger capacity than 40 ml can be created. There are there being a possibility of receiving the long-term infection by a lasting endermic access port, and a possibility that implant surgical operation time may become long in this system. A patch has oblong physical shape shape, the blood side of a chamber comprises a flexible balloon, it pierces through the rigid lining of a chamber, and the distraction of the pneumatic line (it is also hereafter called a hose) for expanding and shrinking a balloon is carried out. The circumference of the rigid lining of a chamber serves as a flange which provides the edge for suturing a patch to an arterial wall. It is endermically run through with a hose by the skin surface through the skin port designed specially. Expansion and contraction of the balloon under operation are performed using the exterior air pump combined with the dynamical artery patch in an artery. When not carrying out a pulse drive when a balloon does not carry out a pulse drive or, the safety of a pump is guaranteed by making a blood flow release an artery. In a standby mode, a chamber is shrunk for the inside of a balloon as atmospheric pressure power lower than arterial pressure.

[0008]In US,4,938,766,B, adding a flexibility chamber to an arterial system is indicated. If an artery hardens, the flexibility of a pipe will fall, and there is a possibility that the after load added to the heart may increase. By adding a flexibility chamber, the influence of arteriosclerosis retreats a little and the burden of the heart decreases. According to US,4,938,766,B, such a device is used in order to support the left ventricle generally. Some shape of a flexibility chamber is indicated and various implanting method is also taught. This device may be classified as each machinery clip of the single-port chamber type attached to an artery, a dual port flow through chamber type, and a spring load type. A valve may be contained in the entrance side of a flexibility chamber in the thing of design shape with flow through composition. This valve is for preventing a back run and making blood discharge preferentially from a flexibility chamber towards a more desirable position.

[0009]That by which pumping in a diastole is directly referred to typically with a ventricular assist system (it is also hereafter called VAD) carries out. VAD which has flow through composition and carries out direct conversion of the electrical energy to mechanical energy is the most suitable as conventional technology indicated on these Descriptions. The device which compresses a toroid flow lead pipe into US,4,091,471,B mechanically by extracting an inside diameter, and extrudes the compressed lead pipe outside keeping an outer diameter from expanding is indicated. Prevention from expansion of an outer diameter is realized by pressurizing the center portion to which the seal of the toroid center position was carried out. In US,4,250,872,B, the pumping chamber of the flow through composition curtailed with the fluid for application of pressure is indicated. The pumping chamber of this United States patent

mainly controls compression of a pumping chamber based on change of the thickness of a pumping-chamber wall. In US,5,089,016,B, the device of the toroid design shape of the flow through composition which compresses a toroid-shaped pumping chamber using a fluid pressure pumping fluid is indicated. This device may have a valve in each position of the entrance of a pumping chamber, and an exit. Blood pumping is attained by being compressed from all the circumferencial directions in itself [pumping-chamber]. However, in order to minimize the wall stress in a pumping chamber, it is preferred by reinforcing the opposite hand of a wall that a pumping chamber is extracted towards one direction.

[0010]The implant is carried out to document (Ann Thracic Surg, 59:S46-S51-1995) which document (Curculation, 89:2980-2914-1994) which Frazier others published, and McCarthy others published into an upper left part abdominal wall, respectively, The blood pump device which has a circular pumping chamber of the diaphram drive type which heartbeat blood volume is 83 ml and is obtained is indicated. This circular pumping chamber receives the blood from the lead pipe which ran through with the crowning of the left ventricle. Diaphram or a drive film may be driven with pneumatic pressure or the electric motor which drives a single rotation roll cam mechanism. The pumping chamber is circular and, in any case, a drive line is run through with it by the skin. Since the non-blood side of diaphram is aerated by the atmosphere via a skin port, it can be appropriately filled up with a pumping chamber. In the blood pump device indicated to US,5,569,156,B, diaphram has the non-blood side in contact with the hydraulic fluid by which active pumping should be carried out to another capacity chamber (it is also hereafter called VDC) during pumping-chamber restoration. This blood pump device also has each port of an entrance and an exit which intersects perpendicularly with the drive film of a blood pump device.

[0011]The separate flexibility chamber which is arranged in a pleural cavity and is [non-blood contact side of the diaphram of a blood chamber] open for free passage by an airtight pipe means in document (ASAIO Transactions, 35:402-404-1989) besides Ramasamy and by which gas charging was carried out is illustrated. In this flexibility chamber, in order to carry out facilitating of the gas charging, it is necessary to carry out facilitating of the blood inflow for the non-blood contact side of diaphram as a pressure near atmospheric pressure or atmospheric pressure. The artificial VDA pumping chamber accompanied by related electronic parts or drive mechanism is not still miniaturized fully, in order to carry out the implant thoroughly. Various leads must be rather inserted in the skin and a pumping chamber must be connected with an external drive mechanism. In order to be able to fill up a pumping chamber with blood easily, it is necessary to reduce the pressure which opposes. Using the middle hydraulic fluid combined with the aeration and the capacity chamber which carried out the implant, or VDC to the separate flexibility chamber which filled up each above-mentioned document with the gas in the aeration to three means for realizing this failure of pressure, i.e., the atmospheric

pressure power which lets the skin pass, and the thorax is indicated. This pumping chamber receives the blood from a left-ventricle crowning, and the blood which won popularity is sent into the pumping chamber indicated in document besides Frazuer by the main artery across a channel parallel to the left ventricle, and it has a blood channel parallel to the left ventricle in this way.

[0012]

[Problem(s) to be Solved by the Invention]Therefore, the issue which it is going to solve is fulfilling the demand over a blood pump device small enough which the implant's is thoroughly carried out with related electronic parts, and can avoid fear of the infection relevant to an endermic lead. Other issues which it is going to solve are providing the blood pump device which is a thing of which chamber gestalt of the separate chamber which connected with the pump using the part or gastight envelope of a pump, and should not need the 2nd chamber for that and flexibility. Furthermore it is going to solve, other SUBJECT is providing the blood pump device which drives a pump for the blood which received blood and won popularity, and returns blood as a much high-pressure thing rather than it in a distant main artery under filling pressure low from a main artery base in contrast with a parallel joint passage at an ascending aorta. With the left ventricle, such a connection configuration may be referred to as it is "serial".

[0013]

[Means for Solving the Problem]A blood pump device according to this invention in which implant is possible may contain pump housing which has pump parts and a drive chamber which stores drive mechanism. Pump parts may be the plate members of flatness or the shape of a glass combinable with pump housing. Drive mechanism may contain an electric servomotor which has a stator, a rotor, and an output shaft. An output shaft is combinable with an eccentric shaft which may have a cam part. a pumping arm which a cam part may be a roll cam and has an end part which follows a cam can be provided -- an omitted portion of a pumping arm -- housing -- a pivot -- it can equip rotatably. a pivot -- an end of a pumping arm attached rotatably contacts a cam surface intermittently, and the surface of an end of a pumping arm acts as a cam follower. The other end of a pumping arm is combinable with a movable plate. A compressive blood chamber which combined an entrance and an exit with the circulatory system can be made to pinch between a glass shaped part and a movable plate. A valve for supporting that arterial blood passes a blood chamber only in one way certainly can be provided in an outlet position of a blood chamber. In this way, if a cam is rotated and a cam rotates, a pumping arm will carry out [center of rotation /, i.e. a center / omitted portion / which was fixed /,] the pivot rotation of the electric servomotor. A movable plate compresses and releases a blood chamber periodically by pivot motion of a pumping arm, and pumping of the blood is carried out through the circulatory system. It is preferred that

carry out the implant of the movable plate side of a blood pump device to a position which adjoins a lung, and a movable plate moves, blood faces that pumping is carried out and a lung moves with this movable plate. Therefore, a lung can be used as a flexibility chamber for a blood pump device. After all, the necessity of providing a flexibility chamber independently is lost. It is preferred to combine a reduction gear between an electric servomotor and an eccentric shaft. A reduction gear may have gear array constitution with four planetary gears. A metal bellows member for sealing seals can be provided in the circumference of an omitted portion of a drive chamber and a pumping arm. A bellows member prevents drive mechanism from carrying out the seal of the drive chamber in the circumference of an end of a pumping arm, and contacting body fluid by that cause. A bellows member carries out the sealing seal of the space, and it provides a means for transmitting movement of a driving assembly, without tearing such a sealing seal.

[0014]Some blood pump devices can surround all with an envelopment bag made from Polymer Division preferably filled up with an isotonic salt water solution, and the parent organization surface which surround an organization can be made to provide. An envelopment bag prevents an organization also from being involved in a movable part of a blood pump device. A position sensing device for determining relative blood volume in a blood chamber can be positioned. Both relative blood volume in a blood chamber can serve as information which displays blood volume and cam positions in a blood chamber. Especially this information can be used in order to control motor speed and to optimize a pump operation, when blood discharge from a blood chamber should be started. The implant of the blood pump device may be carried out in various composition. A standard artificial blood vessel can be used for an entrance and an exit. Exit cannula is joined to a thorax ascending aorta, entrance cannula is joined at a thorax ascending aorta (in series), only one valve is provided in exit cannula, or it can join (in parallel) and an integral-type valve can be provided in each cannula of an entrance and an exit at a crowning of left ventricle (LV).

[0015]The implant of the electronic control object which carried out the sealing seal for making some functions for controlling operation of a blood pump device provide can also be carried out. An ECG lead can be combined with the heart and an electronic control object can be made to supply a signal. Such a signal can be used instancy for ****** in order to control **-SHINGU. The same ECG lead is used, and if required, pacing of a patient's heart can also be carried out. Since many of cardiac insufficiency patients have the high danger of starting ventricular fibrillation (sudden cardiac death), they can also pull out electric ****** / ****** lead from an electronic control object. Electrical energy to this electronic control object can be supplied via endermic energy and a data transmitting system (it is also hereafter called TEDTS). TEDTS can use a hypodermic (secondary) coil which carried out the encapsulation. A hypodermic coil is connected to an electronic control object after all. An external (primary)

coil which agrees with a hypodermic coil can be fixed to a patient's skin, energy can be transmitted to an electronic magnetism target at a secondary coil, and an electronic control object can be operated. It is also possible to use such a coil pair doubling object in order to send data in both directions between an electronic control object, and external detection and a program device. Such one system for sending electric power and data endermically is indicated to US,5,630,836,B. A battery of an electronic control object may be charged during the usual TEDTS operation. When external coiling of TEDTS was removed from a patient's skin, or that was not right and electric power of TEDTS declines, electric power required in order that a battery pack of an electronic control object may operate an in-plant system for several hours can be provided.

[0016]

[Embodiment of the Invention]With reference to Drawings, the blood pump device 10 in which the perfect implant is possible to drawing 7 is illustrated by explaining this invention from drawing 1, It is combined on operation with the component parts 200 relevant to a patient's circulatory system, for example, an electronic control object, (it is also hereafter called EC), the battery pack 210, and TEDTS220. the blood pump device 10 can carry out the implant to which a thorax on either side -- a parallel form -- or it is connectable with the circulatory system under series constitution. The right thorax implant composition for assisting drawing 1 and drawing 5 with the parallel form of another mode in the ventricle is illustrated. The left thorax implant composition for assisting drawing 4 with a parallel form in the ventricle is illustrated. Also in which thorax implant on either side, the implant of the blood pump device 10 can be carried out under the state where blood takes a channel from a left-ventricle crowning to an ascending aorta in the thorax of a human body (or animals other than a human body). The blood pump device 10 can be positioned so that a lung may push the operation side of this blood pump device a little. By arranging in this way, the blood pump device 10 becomes the thing of automatic flexibility which used lung tissue, and the necessity over a separate flexibility chamber is eliminated. A pumping function also relates to a target directly further with a blood flow lead pipe.

[0017]The blood pump device 10 of arbitrary composition can be arranged inside a breast wall in the position of the almost same height as the heart, as shown in drawing 2 and drawing 3. The blood pump device's 10 pressure of the blood chamber 20 will show that the blood chamber 20 comes to be thin by the discharged blood volume. In this way, a lung will act as a flexibility chamber for the blood pump device 10. This brings about the clear profits which excel the blood pump device assembly from the former which needs the artificial chamber which carried out gas charging, in order to obtain flexibility. If time passes, by discharge, gas volume needs to be lost, and it needs to be periodically re-filled up with an artificial chamber after all, and it needs to maintain the capability. It is too large for including a blood pump device

assembly in a thorax in a system conventionally [most]. Such conventionally, in a system, blood pump device assemblies are completely different component parts, and if a flexibility chamber has space, the implant of it may be carried out even to somewhere else. Therefore, the airtight tubular terminal area for connecting a flexibility chamber to a blood pump device assembly is provided. The component parts by which the implant is carried out decrease, and there is also little space required for the implant much, and they can be managed with the blood pump device of automatic flexibility. Therefore, this invention is substantial much space efficiency-like [assembly / from the former / which needs a flexibility chamber separately / blood pump device].

[0018]Much profits can be obtained by obtaining flexibility using the lung space in the thorax. For example, since the pressure in lung space is very close to atmospheric pressure, the ideal situation for being filled up with a pumping chamber is provided, it is one of these and the necessity over a flexibility chamber is eliminated. It cannot be overemphasized that a direction with few parts for a human body which need to carry out the implant is good. The lung is extremely rich in flexibility, and on the whole, it can bear, without receiving or spoiling an adverse effect to a lung function also to some compression and expansion. Unlike an artificial flexibility chamber, the lung does not need to produce "leaking", therefore does not need to be periodically re-filled up with it. And the thorax protects a blood pump device. A blood pump device is the inside of a breast wall, and as shown in drawing 4 in the state of adjoining the heart and contacting a rib, it may be arranged. Interference with a lung function is a minimum grade, and occupation space is efficiently used by that a pumping chamber is flat on the whole.

[0019]As shown in the blood pump device 10 at drawing 7 and drawing 8, it can also attach under series constitution at the circulatory system. The ventricular assist system from the former, i.e., VAD, is typically attached at the circulatory system under a parallel form as shown in drawing 1, drawing 5, and drawing 6, and an entrance conduit receives the blood from the left-ventricle crowning 2 in that case. In such array constitution, blood flows into a blood pump device from a ventricle pars basilaris ossis occipitalis. When it is supposed that the blood channel in the conventional VDA is parallel to the blood channel of the usual left ventricle, therefore the blood pump device of VAD breaks down, these parallel blood channels have a possibility of getting it blocked by a thrombus. In the case of series constitution, if a blood pump device breaks down, a blood channel will become longer than usual, but since blood continues being sent to a blood pump device, a thrombus becomes difficult to happen. Therefore, series constitution is safer as compared with a parallel form, even when a blood pump device breaks down. It replaces with the blood from the left ventricle being sent out from the crowning of the left ventricle in a parallel form, so that that may be right, Usually, since it is sent out to a target through an aortic valve, a possibility of getting a blood flow blocked within a

blood pump device at the time of blood pump device failure not only decreases, but the high danger of getting a blood flow blocked within the left ventricle decreases. Other strong points in the case of considering it as series constitution are that what is necessary is just to provide only one valve in the exit pipe of a blood pump device. By contrast, it is necessary to provide one each and a total of two valves to each lead pipe of an entrance and an exit in a parallel form. or [providing such a valve in the inside of a long lead pipe] -- or a part of connector assembly is used. Mechanical or, in any case, the valve of living thing replaceability is used. However, what is necessary is just to position only one valve in an exit pipe, since the original aortic valve of the heart can act as an inlet valve of a blood pump device in the blood pump device of series constitution.

[0020]The conventional technique for attaching a lead pipe to the circulatory system is illustrated by drawing 12 from drawing 9. A lead pipe is connectable with a blood pump device by suturing using the quick connector which used the coupling frame of spool form or was manufactured beforehand. The coupling frame of spool form covers this coupling frame, and has the design shape which has the artificial blood vessel put firmly on coupling frame by a band or ligation. A quick connector has an end with which it agrees for combining a lead pipe with a blood pump device. The termination of the end of the blood pump device 10 and the end of the condom made from polyurethane is carried out in the position of these connecting parts irrespective of the form of the connecting part to be used.

[0021]The implant technique in series constitution is illustrated by drawing 11 from drawing 9, and it is exposed for the connection with an inflow lead pipe of a thorax ascending aorta. While carrying out the pinch stop of the one segment of an arterial wall using a SATINSUKI (satinski) clamp, the usual artery flow is maintained without blocking. On the occasion of preparation incorporating an inflow lead pipe, the section in which the artery carried out the clamp stop is cut open for a long time. Subsequently, the end of an inflow lead pipe is sutured to the flank of an artery using surgical closure. The clamp of the approaching side is removed and air is extracted from an inflow lead pipe using the hypodermic needle. After carrying out air extraction, the clamp by the side of a distant place is removed. Thereby, the artery separation part or constriction part for sending the blood from the left ventricle in in-series through a blood pump device in an ascending artery at an arterial system is created. In order to connect the lead pipe of series constitution to an artery, junction between ends to a heart bypass can also be used.

[0022]The implant technique in a parallel form is shown in drawing 14 from drawing 12, and it is exposed for cannula inclusion of one segment of a thorax ascending aorta. The pinch stop of the one segment of an arterial wall is carried out using a single SATINSUKI (satinski) clamp, and on the other hand, the usual artery flow is maintained, without blocking. The section in which the artery carried out the clamp stop on the occasion of preparation incorporating

cannula is cut open for a long time, it ranks second and the end of cannula is sutured to the flank of an artery using surgical closure. The sutured cannula is used as an exit pipe of a blood pump device. Subsequently, cannula is built into a left-ventricle crowning and this cannula is connected to the entrance conduit of a blood pump device. Since the blood pump device combined by this parallel form has fear of air ****** by having an opening in the left-ventricle crowning, probably the heart bypass for the implant is required for it.

[0023]The quick connector assembly 80 from the former is shown in drawing 15 and drawing 16. The entrance 24 or the exit 22 of the blood chamber 20 is combined with the actuator septum 84. The sleeve 88 for a lock can be attached to the actuator septum 84, and it can be considered as the fixed tip for the quick connecting part of the quick connector assembly 80. The artificial blood vessel 110 is joinable to the base material ring 86. The base material colors 92 surround the base material ring 86, and it may have the two pins 90 for a lock of one. The compression spring 94 can be formed between the base material ring 86 and the base material color 92. The compression spring 94 is compressed between the base material ring 86 and the base material color 92, and is held by the pin 90 for a lock at an appropriate position. The pin 90 for a lock is slidable in the inside of the long hole 98 in the base material ring 86. The O-ring 82 can also be arranged between the base material ring 86 and the base material color 92. The O-ring 82 is held with the base material color 92 at an appropriate position. Another O-ring 82 can be arranged between the base material color 92 and the sleeve 88 for a lock. Thus, the seal of the quick connector assembly 80 may be carried out to body fluid. The actuator septum 84, the entrance conduit 24 or the exit pipe 22, the O-ring 82, and the sleeve 88 for a lock are contained in the actuator side edge part of the quick connector assembly 80. The blood flow lead pipe 110, i.e., an artificial blood vessel, the pin 90 for a lock, the base material color 92, the compression spring 94, and the O-ring 82 are contained in the lead pipe side edge part of the quick connector assembly 80. On the occasion of an assembly, a lead pipe side edge part and an actuator side edge part are brought near, and it lets the pin 90 for a lock pass to the long hole 100 of the sleeve 88 for a lock. Subsequently, each end is advanced, the base material color 92 is rotated clockwise, and the pin 90 for a lock is moved along the passage of the long hole 100 of the sleeve 88 for a lock. If connection is completed, the seal of the inside will be carried out from a human body, and, as it thinks best, a quick connector assembly will be held by the O-ring 82 with the pin 90 for a lock, and the compression spring 94. Please understand that the quick connector assembly in another mode can be used. It is important that a delicate circular connecting part can be sutured surgically, without receiving the physical interference by a pump existing by using a quick connector assembly. The surgeon can continue at the suture which connects a lead pipe with the circulatory system, and can carry a pump quickly using a quick connector assembly.

[0024]The blood chamber 20 is producible from polyurethane of the medicine grade which has

elasticity compressibility and living thing stability, for example, polyurethane of form which is indicated to US,5,133,742,B. An one surface pattern may be given so that the organization chart side which extends in the inside for the inner surface in contact with the blood of the blood chamber 20 to form a biological blood contact surface may be provided. A surface pattern may consist of the staple fiber by which orientation was carried out by intersecting perpendicularly with the surface of the blood chamber 20. Such a surface pattern may be indicated to US,751,839,B. The surface encaustic attachment by textiles can promote the manifestation of biological intima lining. As for intima lining, it is preferred to carry out the distraction of the blood chamber 20 and the artificial blood vessel 110 whole without a stitch. The artificial blood vessel made from Dacron (brand name) is also because the organization which extends inside is made to reveal preferably and the biological surface may be produced inside an artificial blood vessel by that cause. As the blood chamber 20, on the whole, has flow through type design shape and a vortex or a flow stagnation zone is minimized, change of a cross-section area may be the minimum.

[0025]It may be formed by any of each in-series or parallel circulation combining form type it chooses again they are by whether the blood chamber 20 positions the blood pump device 10 to which [of the thorax] side by having rhombus shape substantially in itself with various composition. For example, some different composition is illustrated by drawing 19 from drawing 17. The composition for connecting a blood chamber with thorax right-hand side in parallel form is illustrated by drawing 17. In the steel things connected with thorax left-hand side in parallel, a blood chamber makes what is shown in drawing 17, and a mirror image. In order to carry out a series connection to thorax right-hand side, the blood chamber 20 can become a thing of composition of positioning substantially [mutual] an entrance and an exit as shown in drawing 19 in an opposite hand. However, the blood chamber 20 may be formed in non-flow through type "blind porch" composition which is illustrated to drawing 18 in another mode which carried out the series connection to thorax right-hand side. Irrespective of specific composition, the material composition of the blood chamber 20 is the same, and is acquired. That and the blood chamber 20 may be produced from polyurethane of the medicine grade referred to previously with which composition.

[0026]The blood pump device which follows this invention with reference to drawing 26 from drawing 20 is shown, and the pump housing 13 has the glass-like portion 15, the drive chamber 18, the blood chamber 20, and drive mechanism. The pumping arm 33 and the movable plate 28 are contained in drive mechanism. As for the pump housing 13, the pumping arm 33, and the movable plate 28, it is preferred to constitute all from titanium. A blood chamber can be positioned in the glass-like portion 15 of the pump housing 13. The glass-like portion 15 may have the opening 16 for the entrance 22 of the blood chamber 20, and the exit 24. Although the glass-like portion 15 is shown in the shape of a glass by a diagram, a bottom

plate flat on the whole can also be used. Except for the movable plate 28 having surface area smaller desirable a little than the surface of the blood chamber 20 where this movable plate 28 is pushed, it may have the blood chamber 20 and shape corresponding on the whole. It is preferred to face to carry out the implant of the blood pump device 10 to a patient, and to position so that at least some movable plates of the blood pump device 10 may adjoin at least a part of a patient's lung 5 and it may be positioned. In order that the movable plate 28 may carry out pumping of the blood by doing so, the lung 5 can be faced moving so that it may illustrate from drawing 2 to drawing 3, and it can be moved now with the movable plate 28. After all, a changed part of the capacity of the blood pump device 10 is compensated with a lung acting as a flexibility chamber for this blood pump device 10.

[0027]As for the edge of the movable plate 28, as shown in drawing 21 and drawing 23 thru/or drawing 24, when the blood chamber 20 is compressed, in order to keep stress from concentrating on the edge position of the movable plate 28, it is preferred to have the curvilinear shape which separates from the blood chamber 20. The blood chamber 20 and the size shape of the movable plate 28 are faced the blood chamber 20 being pressurized and being compressed, and they can be optimized so that the bending stress and hoop tension which are produced into the flexible portion of the blood chamber 20 may become the minimum. The blood chamber 20 should be repeatedly deformable and it should be possible to return to the state before modification qualitative moreover in addition as a matter of fact. The bending stress can cope with it, when the blood chamber 20 chooses carefully the proper wall thickness which can be equal to total compression. As for the entrance 22 and the exit 24 of the blood chamber 20, it is preferred to position in the flat surface of the greatest projection part of the blood chamber 20. After all, the blood chamber 20 can become a thing of the thinnest outline.

[0028]Theoretically, in order to optimize the blood chamber 20, the necessity of taking many complicated phenomena into consideration may arise. The deviated amount which the blood chamber 20 receives in the 1st first is large as shown in drawing 23 and drawing 24, but it is being unable to explain this phenomenon by the principle of the simple intensity of material. It is because the ingredient of the action of the material showing big modification and deflection is omitted for simplification. It is the cause for which the point said that a "schoolbook" answer is a thing to easy shape and ingredient also causes complication to the specific three-dimensional shape of the predetermined blood chamber 20 being explained. Are the characteristic that Polymer Division used for the 2nd by this invention has the nonlinear relation between stress and a strain having, and to the 3rd. It is a point which the blood chamber 20 says that itself is a complicated contact phenomenon and the local deformation for bending around the edge of the movable plate 28 is a thing directly in connection with the shape of the movable plate 28, or the thickness of the blood chamber 20. One practical

method of evaluating the blood chamber 20 uses finite-element analysis, taking such a factor into consideration. In this solution, the ingredient which poses a problem is decomposed into a small and simple portion (element) all the time. Subsequently, each element is solved simultaneously, it faces formulating an element, and complexity is explained. To the problem mentioned above, a remarkable computer resource and computation time are needed.

[0029]The blood chamber 20 of this invention receives simultaneously the strain which bends during operation of the blood pump device 10, and originates in a pressure. As stated previously, such bending is involved in the shape of the edge of the movable plate 28, and the thickness of the blood chamber 20. It is decided by length S_F of the portion which also has a strain produced by blood pumping in the state of receiving not only the thickness of the blood chamber 20 but pressure load. In short, the pressure load added to the blood chamber 20 becomes large, so that this length S_F becomes long. If the blood chamber 20 is thickened, the amount of strains resulting from a pressure will decrease, but the amount of strains at the time of the blood chamber 20 bending around the movable plate 28 increases. In this way, bending and making each strain by a pressure balance is included in a design problem. Subsequently, it is necessary to determine blood chamber 20 shape of bringing about the best performance, by changing the edge shape of the movable plate 28, partial length S_F of the blood chamber 20, and the chamber width in length S_F.

[0030]Typically, the component parts made from Polymer Division have the design shape which maintains the predetermined strain level over the life of these component parts. Therefore, it may be necessary to get to know the maximum amount of strains permitted to a predetermined material and load frequency. According to the conventional research, it was shown that a maximum of 15% of strain may be permitted to 2 million cycles to the polyurethane used for this invention. After all, this strain level can be used as design allowable maximum stress deformation of the component parts made from polyurethane of this invention.

[0031]With reference to drawing 25 and drawing 26, drive mechanism may contain preferably the servo motor 56 of an electric type connected with the reduction gear 70 for rotating the eccentric shaft 47. The eccentric shaft 47 drives the pumping arm 33 and the movable plate 28, and can carry out pumping of the blood. The stator portion 58 and the rotor portion 60 are contained in the servo motor 56. ** arrival of the stator portion 58 is carried out to housing, and the rotor portion 60 may contain the output shaft 62 for rotating the eccentric shaft 47 and generating a pumping action. the servo motor 56 -- a power supply -- and -- or the electric power coupling 79 for connecting with EC200 can be formed. The servo motor 56 may have various sizes or aspect ratios. As for the servo motor 56, what can carry out continuous rotation by about 2,000 to 3,000 RPM is preferred. Sierracin/Magnedyne of California Carlsbad

can manufacture the servo motor 56, for example. The servo motor 56 carries out pumping of the blood at speed of per minute 120 beats, and, as for the cylinder capacity of a blood pump device, it is preferred that it is 60-80 ml. In addition, a blood pump device resists the pressure in the range of human being's arterial pressure power in the blood in cylinder capacity, and should move blood. In the case of a cardiac insufficiency patient, generally, such arterial pressure power ranges are about 160 mmHg(s) in the maximum. Such a standard can be used and the design of blood pump device 10 blood chamber 20, pumping arm 33, servo motor 56, and reduction gear 70 and other component parts can be optimized. the calorific value which silence-operates the servo motor 56 and the reduction gear 70, and may be received -- and it should be preferably designed also for the long operation life in the maintenance free situation for at least five years.

[0032]As for the reduction gear 70, it is preferred to join together between the output shaft 62 and the eccentric shaft 47. As for the reduction gear 70, it is preferred that it is a planetary-gear-type reduction gear which changes rotational movement of the servo motor 56 into the number of cycles between per minute about 80 and 120 as gear ratio best shown in drawing 26 of 25:1. The speed of the servo motor 56 and the ratio of the reduction gear 70 can be chosen so that energy efficiency may be attained and the compactest drive mechanism may be provided. One rotation of the output shaft of the reduction gear 70 operates one process of blood pump devices 10, and this distance operation arises in the range which is per minute about 60 to 120 cycle. Although some planetary-gear type reduction gears which can carry out commercial acquisition are various, in order to reconcile minimization of size shape, and maximization of efficiency, it is preferred to use the thing of an order design. The planetary-gear type reduction gear 70 may be a thing of 3 gear differential (it is also hereafter called TGD) mold as shown in drawing 26. Although the gear type reduction gear of other forms can be used, TGD is preferred from especially small being energy efficiency-like. Inside flywheel starter gear may be contained in the reduction gear 70 of this form. It is known that inside flywheel starter gear have few slides at the time of engagement, and the contact ratio for transmitting load to a target more gradually is high. TGD is long-life, and more efficient than the reduction gear of other forms, and the load support capacity to a prescribed dimension is not only large, but it a low noise. Rather than a more general 4 gear differential type thing, there are few a gears, therefore they can miniaturize TGD. As for a planetary gear, it is preferred to use four pieces. A load passage will be 4 times by doing so, and it enables the number of planetary gears to miniaturize the whole shape all the time rather than fewer things.

[0033]The output shaft of the reduction gear 70 is combinable with the eccentric shaft 47. The eccentric shaft 47 may have the input part 48 which attached the flywheel-starter-gear portion 68 which may be driven with the reduction gear 70 so that it may be best shown in drawing 25. The pumping arm 33 contacts in the form where it rides on the circumference of an end of the

eccentric shaft 47. After all, although the eccentric shaft 47 drives the pumping arm 33 in a pumping process, the inside of the return process [it fills up with the blood chamber 20] of a between carries out the free movement of the pumping arm 33, without being restrained. The cam which is the roll bearing 52 and is obtained is attached to the end of the eccentric shaft 47, and the end of the pumping arm 33 follows for this cam. The center of rotation of the eccentric shaft 47 is shown as C_{axis}.

[0034]As for the pumping arm 33, it is preferred to carry out orientation into the flat surface which intersects perpendicularly with the axis of rotation of a servo motor and a reduction gear. the omitted portion of the pumping arm 33 -- a pivot -- the bearing 43 can be formed in the position of center-of-rotation C_{arm} of the portion attached rotatably. It is preferred to use the sleeve made from Polymer Division which low abrasiveness does not illustrate by non-corrosiveness as a bearing for combining the pumping arm 33 with the movable plate 28. Materials desirable for this connecting part are PPS sleeve material and 316 stainless steel. The end of the side in contact with the cam surface of the pumping arm 33 operates as the cam follower 45. The pumping arm 33 is periodically rocked, as best shown in drawing 22 focusing on the center-of-rotation C_{arm}, and periodic pumping of the blood chamber 20 is attained as the cam 52 rotates on an eccentric shaft. The ratio of the distance from the center of rotation of the pumping arm 33 which carries out pivot motion to each end is expressed with drawing 21 as D_1 and D_2, and determines possible lever ratio in the predetermined geometrical form of the pumping arm 33. As for distance D_1 from the center of rotation of the pumping arm 33 to the movable plate 28, what is larger than the distance to the surface of the cam 52 is preferred. The torque conditions for the eccentric shaft 47 can become the lever ratio of a pivot arm with what also has a quite big twist. However, by that cause, the hardware for energy conversion (a servo motor, a reduction gear, a cam) can be brought close to center-of-rotation C_{axis} of the eccentric shaft 47, and can be positioned now, and it enables much more miniaturization of drive mechanism. It is preferred to form the position sensing device 39 in the position which adjoins the omitted portion of the pumping arm 33. The position sensing device 39 may be an eddy current sensor for detecting the position change of the pumping arm 33, for example. The relative capacitor of the blood in the blood chamber 20 can be determined from the position change of the pumping arm 33, and the position of the eccentric shaft 47 or the cam 52 can be determined.

[0035]The movable plate 28 may have the central joint point 29 which can serve as an installation part of the end 41 of the pumping arm 33. It can pierce through punching in a movable plate, and punching of the end 41 of the pumping arm 33, and the pin 30 can be arranged. Thereby, the pin 30 hinges the pumping arm 33 on the movable plate 28. As for the

pumping arm 33, it is preferred to rock the inside of the flat surface which intersects perpendicularly with the movable plate 28. By having hinged the pumping arm 33, orientation of the movable plate 28 may be carried out in the direction that the strain of the blood chamber 20 may be minimized during process operation, in itself. As for center-of-rotation C_{arm} of the pumping arm 33, providing in a drive chamber is preferred.

[0036]Since the surface of the cam 52 contacts the pumping arm 33 intermittently, the period only until between the compression phases of cam rotation operates and blood is [drive mechanism] full of the blood chamber 20 even in such a case operates. In this way, the blood pump device 10 carries out pumping only of the blood with which the blood chamber 20 was filled up between the retreat phases of a cam surface. Thus, the movable plate 28 is separated from a servo motor, while the blood chamber 20 is full, and moreover, in addition, it moves up and down continuously, without carrying out pumping of the blood chamber 20. the case where pumping of the blood chamber 20 with which this is not filled thoroughly is carried out -- the film of the blood chamber 20 -- ** -- better or ******** occurs -- and -- or the pressure of the left ventricle is prevented from declining superfluously.

[0037]The sealing seal of the center-of-rotation C_{arm} of the pumping arm 33 and the drive chamber 18 can be covered and carried out, and the SHIRUBE rose 38 for keeping away body fluid from drive mechanism can be formed preferably. The end caps 36 and 37 can be established in which end of the SHIRUBE rose 38. The end cap 37 of front sides has the opening by which the seal was carried out to the circumference of the pumping arm 33, and the bellows portion 35 leads to the drive chamber 18 through this opening. As for the SHIRUBE rose 38, producing from titanium is preferred. The SHIRUBE rose 38 is an important characterizing portion from this enabling the component parts for energy conversion to have lubrication fluid of abiosis compatibility, and corrosive hard steel being shielded from the salt water (saline) environment of a human body. By forming the SHIRUBE rose 38, a possibility that a gear, a bearing, and a motor may corrode can decrease greatly. The corrosion of such parts may be generated when body fluid diffuses in the drive chamber 18. Although it seals the drive chamber 18, if the transfer to the movable plate 28 is possible for the SHIRUBE rose 38, in addition, it closes the mechanical energy of the servo motor 56. The bearing made from the hardened steel which operates about five years or more under protection lubricous environment, and a gear and other parts can be used now by the sealing seal of the motor drive assembly being carried out. It is desirable to use the parts made from hardened steel from the ability for it to be efficient and transmit the power energy inputted into an electric motor to blood work by the bearing made from hardened steel, or the rolling friction of another gear and motor driving section article. By approaching center-of-rotation C_{axis}, and positioning the hardware for energy conversion (a servo motor, a reduction gear, a cam), it

becomes possible to miniaturize the whole drive mechanism more, and it minimizes movement induced by the SHIRUBE rose. After all, the sealing seal of the drive mechanism can be carried out now more practical.

[0038]By forming the envelopment bag 105 made from Polymer Division in the circumference of the blood pump device 10, as shown in drawing 2 and 3, it is preferred to provide the surface which adapts itself to the organization of the patient who surround the blood pump device 10. It is preferred that this envelopment bag 105 is surrounded with the pumping arm 33 and the movable plate 28 at least, and an organization is made not to be involved in in the operating space of the pumping arm 33. elastic deformation is free for the envelopment bag 105, it is boiled under a state which differential pressure does not produce the upper part and around the envelopment bag 105, and moves with the movable plate 28. The envelopment bag 105 prevents and carries out growth of the organization towards in the field of this envelopment bag 105, and it prevents beforehand connection of the pumping arm 33 to such an organization. The blood pump device 10 whole can also be stored to envelopment bag 105 inside, if required.

[0039]Even if it is which parallel or in-series blood flow composition, the blood pump device 10 can be operated without making it synchronize synchronizing with the heart 1. In synchronized operation, typically, the blood pump device 10 discharges blood, whenever the left ventricle contracts. The timing of blood discharge of the blood pump device 10 is controlled by detecting the degree (QRS) of electrical activity of the heart in case the left ventricle discharges blood (contraction). When this degree of electrical activity is detected, the blood pump device 10 can discharge blood after the time delay preset immediately. However, as for blood discharge of the blood pump device 10, it is preferred to be carried out after the left ventricle finishes blood discharge. In asynchronous operation, the blood pump device 10 often discharges blood regardless of QRS. the time delay back by which it was programmed for example, after QRS signal detection in alignment mode as for the blood pump device 10 -- or it contracts after the stimulative pacing pulse of the electronic control body which carried out the implant. In asynchronous mode, when, as for pumping, the position sensing device 39 detects that the blood chamber changed into the fullness state mostly, the electronic control body 200 may begin, for example.

[0040]In asynchronous mode, it is desirable to operate the servo motor 56 at a comparatively fixed speed, and to minimize the reaction force and power loss relevant to acceleration and deceleration of a gyrating mass. As for the speed of the servo motor 56, when the blood chamber 20 starts each blood elimination phase, it is ideal to adjust so that it may be mostly full. If revolving speed is too slow, the blood chamber 20 will expand before the start of a blood elimination phase, and will restrict the inflow of blood. This has a possibility of heightening the pressure of the left ventricle superfluously. On the contrary, when revolving speed is too quick,

there is too little blood volume discharged from the blood chamber 20, in order to flush the inner surface of the blood chamber 20 appropriately in each cycle. When revolving speed is too quick, the amount of power losses by friction or viscosity becomes large superfluously.
[0041]It is the blood chamber 20 at the start time of each elimination phase, and one means for carrying out optimum control of the motor speed so that it may be mostly full is illustrated by drawing 27. The curve 100 expresses cycle movement of the cam of the output shaft of a reduction gear. In the position shown by the line 102, the cam 52 is drawn thoroughly and the pumping arm 33 is in free floating at the time of the peak filling position being filled up with the blood chamber 20. In the position of the line 103, 180 degrees rotates and the cam 52 compresses the blood chamber 20 into the maximum via the pumping arm 33. The blood chamber 20 is freely full of the blood sent from the left ventricle between the blood inflow phases shown by the line 104. In the blood elimination phase shown by the line 105, the blood chamber 20 is compressed by the operation of a cam and the pumping arm 33, and the blood from the blood chamber 20 is sent out to an artery via a blowdown valve. The lines 106, 107, and 108 show the relative capacitor of the blood within the presumed output value 20 from the position sensing device 39 which detects the position of the pumping arm 33, i.e., a blood chamber. Before starting the blood elimination phase 105, it fills up with the blood chamber 20 when the revolving speed of a motor is too much slow thoroughly, and the line 106 expresses the situation of coming to restrain movement of the pumping arm 33, only when the cam 52 is the position 109. When the line 108 has too quick the revolving speed of a motor, at the start time of the blood elimination phase 105, the blood chamber 20 accepts it selectively, is full, and shows in it the situation where the cam 52 comes to restrain movement of the pumping arm 33 only at the time of the position 111. Motor revolving speed is adjusted properly, it is the blood chamber 20 at the start time of the blood elimination phase 105, and is filled with the line 107 nearly thoroughly, and the cam 52 is the position 110 immediately after the start of the blood elimination phase 105, and the situation of coming to restrain movement of the pumping arm 33 is illustrated. The contact position of the cam / pumping arm expressed with the numbers 109, 110, and 111 of drawing 27, respectively is easily detectable because the differential coefficient of the beginning of the output of the position sensing device 39 becomes negative. The revolving speed of a motor can be adjusted to optimum by raising rotation of a motor, when the contact detected in the detection value of the contact position of a cam and a pumping arm as compared with the ideal contact position 110 is too early, and slowing down motor revolving speed, when contact is too slow.
[0042]In the synchronous mode, the blood chamber 20 synchronizes with a QRS signal, receives the blood between the contraction phases of the left ventricle, and, subsequently to between the expansion phases of the left ventricle, discharges blood. The epicardium from the former or endocardium ECG detection, and a pacing lead can be provided between a patient

and the electronic control body (EC) 200, a cardiac cycle can be supervised, and operation of a blood pump device can be synchronized correctly. The time between the output pulses of the pacer between the detected compound QRS signals is used, and the revolving speed of a motor is controlled so that a cam and a pumping arm end one perfect cycle for every cardiac cycle. The phase to which the motor position about the detected heart cycle relates is adjusted so that the blood elimination phase of the blood chamber 20 may be started, when the abbreviated half of the heart cycle detected when the left ventricle begins to have expanded is passed.

[0043]A defibrillation electrode is provided as 1 component parts of an in-plant system, and it is controllable by EC200 in order to send the therapy shock for irregular **** or the defibrillation. The battery pack which carried out the implant can also use a part of in-plant system, and by the time it is re-filled up using this battery pack at the time of necessity, a blood pump device can be operated for several hours. Usually, the electric power to an in-plant system can be obtained through endermic energy and data transmission (TEDT). The battery pack which carried out the implant and in which re-restoration is possible can provide the electric power for an in-plant system, when it may re-fill up using this TEDT or the electric power supply by TEDT is not performed.

[0044]An electronic control object manages operation of a motor driving body based on the signal received through a pumping arm position sensing device, and arbitrary ECG detection / leads for pacing. the rate response heart rate control for optimizing a CHF patient's cardioassist -- and -- or the physiological sensor for providing control in an AV sequence pacemaker form is incorporable. many of such patients are afflicted by the insufficient condition of the chronotropism -- a rate response ---like -- and -- or AV pacing sequence control may be needed. An ECG electric wire is combinable with an electronic control object via a terminal block. A terminal block can be used also as a connector for a defibrillation therapy electric wire. An electronic control body is operated by a TEDTS subsystem or the electric power supplied with an internal battery pack when the electric power of a TEDTS subsystem declines. A TEDTS subsystem comprises a belt for holding two coils which positioned one side in hypodermic and with which it positioned another side in the outside of the body, an external battery pack, the battery pack of this outside of the body, and a coil to a patient's drum section.

[0045]Another feature of a blood pump device is changed into hemodynamic energy for mechanical energy to attain pumping of blood. As for a step number fundamentally, required in order to transform the electrical energy of a servo motor into the energy for blood work, minimizing generally is desirable. There is inefficiency which produces the loss for every conversion stage in each of energy conversion. In addition to minimizing an energy conversion step number, the efficiency of each conversion stage must be maximized.

[0046]The flow diagram of drawing 28 shows the energy use and efficiency in each of a blood pump device and related system configuration parts. As argued previously, there is efficiency relevant to the stage in each energy transfer stage. If it explains in detail, 3.15-W electric power will be supplied to the motor 325 from the internal electronics 320. Although the 1.57-W electric power which should be sent to the circulatory system 350 remains in the pumping arm 33, the blood chamber 20, and arbitrary heart valves after letting an energy converter pass, this means that conversion efficiency is 45%. Considering that it of most devices which can compete is 10 to 25% of range, this value can be said to be high for a blood pump device. It is thought that what is depended on using the mechanical constitution parts which are not sliding frictions and probably produce energy loss by rolling friction has conversion efficiency higher than usual. The energy of the reduction gear 330 mainly produces a loss by power loss by friction at a bearing. Similarly, power is lost through a bearing also with a cam / pumping arm 335. Sealing seal-ization of the energy converting device is bearing the important role on efficient-izing. Hardened steel or steel "for bearing" which will corrode energy conversion device hardware under the salt water environment of a human body by being isolated from a patient's body can be used now. The component parts created from such a material have good endurance typically to the consumption caused by rolling friction.

[0047]

[Effect of the Invention]1. The demand over a blood pump device small enough which the implant is thoroughly carried out with related electronic parts, and can avoid fear of the infection relevant to an endermic lead is fulfilled.

2. Even if it is a thing of which chamber gestalt of the separate chamber which connected with the pump using the part or gastight envelope of a pump, the blood pump device which should not need the 2nd chamber for flexibility is provided.

3. The blood pump device which receives the blood in low filling pressure from a main artery base, drives a pump, high-voltage-izes blood all the time rather than it in a distant main artery, and returns the blood which won popularity to an ascending aorta in contrast with a parallel joint passage is provided.

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TECHNICAL FIELD

[Field of the Invention]Generally this invention relates to the detailed single-chamber blood pump device in which the perfect implant is possible about the blood pump device in which the implant is possible.

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PRIOR ART

[Description of the Prior Art]A seriously injured cardiac insufficiency condition, i.e., the condition to which it becomes impossible for the heart to send sufficient blood which the body needs, produces a remarkable fall and the immense health care cost of a living standard, and tens of thousands of person dead per year. In order [this] to cope with it sick, pharmacology and many biological intervention measures (those many are patents) like a device were devised, but cardiac insufficiency is main problems of public health as usual in spite of such efforts.

[0003]Cardiac insufficiency is judged because the amount of heart blood **** or the cardiac index is unusually small. The amount of heart blood **** (it is also hereafter called CO) is measured by the blood liter flow per per minute, and calculates the cardiac index (it is also hereafter called CI) as a value which **(ed) the CO value with the patient's surface area of a body (it is also hereafter called BSA). Usually, CI values are 3.0-3.5 during the time of a rest in the daytime, or activity. By a male, by per minute 5.6-6.5 l. and a woman, since a CO value has little surface area of a body, it turns into values a little fewer than it. The CI value of seriously injured cardiac insufficiency is a case of 1.5 to 2.0. In the case of a certain man's average cardiac insufficiency patient whose CO value is per minute 3.27 and whose surface area of a body is 1.87m^2, the blood volume to which the heart rate (it is also hereafter called BPM) of 1.75 and per minute is sent out for a CI value with 80 or 1 beat is an average of 41 ml. This average heartbeat blood volume is conspicuous when CI contrasts with 76 ml whose 3.25 and BPM(s) are the average heartbeat blood volume of the usual male of 80, and there is.
[little]

[0004]There are an inlet valve (mitral valve) and an outlet valve (aortic valve) in the main-process-pump room or left ventricle (it is also hereafter called LV) of the heart. Since an inlet valve is closed while the left ventricle contracts, blood is extruded through an outlet valve and goes into a main artery. Diastolic blood pressure of the left ventricle Although it is 2 - 20mmHg

(it is also hereafter called preload), while having caused cardiac insufficiency, it becomes a value with this higher range. Typically, the left ventricle must resist the aortic pressure which is 70 - 140mmHg (it is also hereafter called an after load), and must discharge blood at the contraction stage. If an after load falls by cardiac insufficiency, heartbeat blood volume increases automatically. This is the Reason a cardiac insufficiency patient is saved with after load fall medicine like ACE depressant.

[0005]There are some which use an opposite pulsation device (it is also hereafter called IABS), for example, an arterial pump, in the general approach which provides a mechanical circulation auxiliary. IABS provides the circulation auxiliary in after load fall form, and is typically used for short-term use (namely, several hours to day). The main benefit of such a device is brought about by making a systole release the left ventricle from load, and increasing the cardiac dilatation pressure for the reperfusion of a coronary artery and the other arteries of a diastole by that cause so that it may be indicated to US,4,733,652,B and 3,692,018, respectively. The patient who needs the treatment of this form is afflicted by the cardiogenic shock and the chronic angina, or the circulation support (Kormos1987 in 1988 besides Nanas) under operation is needed. IABA design shape arranges the bulky balloon drive unit which needs to be stored on the bed of a hospital to a patient's outside of the body.
The use is limited only to an acute use.

[0006]The porch type auxiliary ventricle which has the mechanical means or pneumatic pressure means for carrying out pumping of the stored blood is indicated to US,3,553,736,B and 4,034,742, respectively. Many of both such the auxiliary ventricles have a single access port which provides the entrance and exit for a blood flow. There is a disadvantage that stagnation of a relative flow increases the danger of clot-of-blood formation or the thromboembolism in such design shape. Parallel connection of the auxiliary ventricle of others which have each port of an entrance and an exit both can be carried out to an artery. It may have the valve which meant that the thing of such design shape maximized pumping efficiency (US,4,195,623,B and 4,245,622).

[0007]"a dynamical artery patch" indicated to US,4,630,596,B and 4,051,840 is what is everlastingly attached to an artery -- opposite pulsation -- it has the design shape which provides legal cardioassist. Since this device means long-term use, in order to incorporate this, it needs to cut a patient's thorax open. Like IABP, this device unit is arranged to a patient's outside of the body, and a patch expands by pneumatic pressure through an endermic access port. Unlike IABP, according to this dynamical artery patch, assistance by larger capacity than 40 ml can be created. There are there being a possibility of receiving the long-term infection by a lasting endermic access port, and a possibility that implant surgical operation time may become long in this system. A patch has oblong physical shape shape, the blood side of a

chamber comprises a flexible balloon, it pierces through the rigid lining of a chamber, and the distraction of the pneumatic line (it is also hereafter called a hose) for expanding and shrinking a balloon is carried out. The circumference of the rigid lining of a chamber serves as a flange which provides the edge for suturing a patch to an arterial wall. It is endermically run through with a hose by the skin surface through the skin port designed specially. Expansion and contraction of the balloon under operation are performed using the exterior air pump combined with the dynamical artery patch in an artery. When not carrying out a pulse drive when a balloon does not carry out a pulse drive or, the safety of a pump is guaranteed by making a blood flow release an artery. In a standby mode, a chamber is shrunk for the inside of a balloon as atmospheric pressure power lower than arterial pressure.

[0008]In US,4,938,766,B, adding a flexibility chamber to an arterial system is indicated. If an artery hardens, the flexibility of a pipe will fall, and there is a possibility that the after load added to the heart may increase. By adding a flexibility chamber, the influence of arteriosclerosis retreats a little and the burden of the heart decreases. According to US,4,938,766,B, such a device is used in order to support the left ventricle generally. Some shape of a flexibility chamber is indicated and various implanting method is also taught. This device may be classified as each machinery clip of the single-port chamber type attached to an artery, a dual port flow through chamber type, and a spring load type. A valve may be contained in the entrance side of a flexibility chamber in the thing of design shape with flow through composition. This valve is for preventing a back run and making blood discharge preferentially from a flexibility chamber towards a more desirable position.

[0009]That by which pumping in a diastole is directly referred to typically with a ventricular assist system (it is also hereafter called VAD) carries out. VAD which has flow through composition and carries out direct conversion of the electrical energy to mechanical energy is the most suitable as conventional technology indicated on these Descriptions. The device which compresses a toroid flow lead pipe into US,4,091,471,B mechanically by extracting an inside diameter, and extrudes the compressed lead pipe outside keeping an outer diameter from expanding is indicated. Prevention from expansion of an outer diameter is realized by pressurizing the center portion to which the seal of the toroid center position was carried out. In US,4,250,872,B, the pumping chamber of the flow through composition curtailed with the fluid for application of pressure is indicated. The pumping chamber of this United States patent mainly controls compression of a pumping chamber based on change of the thickness of a pumping-chamber wall. In US,5,089,016,B, the device of the toroid design shape of the flow through composition which compresses a toroid-shaped pumping chamber using a fluid pressure pumping fluid is indicated. This device may have a valve in each position of the entrance of a pumping chamber, and an exit. Blood pumping is attained by being compressed from all the circumferencial directions in itself [pumping-chamber]. However, in order to

minimize the wall stress in a pumping chamber, it is preferred by reinforcing the opposite hand of a wall that a pumping chamber is extracted towards one direction.

[0010]The implant is carried out to document (Ann Thracic Surg, 59:S46-S51-1995) which document (Curculation, 89:2980-2914-1994) which Frazier others published, and McCarthy others published into an upper left part abdominal wall, respectively, The blood pump device which has a circular pumping chamber of the diaphram drive type which heartbeat blood volume is 83 ml and is obtained is indicated. This circular pumping chamber receives the blood from the lead pipe which ran through with the crowning of the left ventricle. Diaphram or a drive film may be driven with pneumatic pressure or the electric motor which drives a single rotation roll cam mechanism. The pumping chamber is circular and, in any case, a drive line is run through with it by the skin. Since the non-blood side of diaphram is aerated by the atmosphere via a skin port, it can be appropriately filled up with a pumping chamber. In the blood pump device indicated to US,5,569,156,B, diaphram has the non-blood side in contact with the hydraulic fluid by which active pumping should be carried out to another capacity chamber (it is also hereafter called VDC) during pumping-chamber restoration. This blood pump device also has each port of an entrance and an exit which intersects perpendicularly with the drive film of a blood pump device.

[0011]The separate flexibility chamber which is arranged in a pleural cavity and is [non-blood contact side of the diaphram of a blood chamber] open for free passage by an airtight pipe means in document (ASAIO Transactions, 35:402-404-1989) besides Ramasamy and by which gas charging was carried out is illustrated. In this flexibility chamber, in order to carry out facilitating of the gas charging, it is necessary to carry out facilitating of the blood inflow for the non-blood contact side of diaphram as a pressure near atmospheric pressure or atmospheric pressure. The artificial VDA pumping chamber accompanied by related electronic parts or drive mechanism is not still miniaturized fully, in order to carry out the implant thoroughly. Various leads must be rather inserted in the skin and a pumping chamber must be connected with an external drive mechanism. In order to be able to fill up a pumping chamber with blood easily, it is necessary to reduce the pressure which opposes. Using the middle hydraulic fluid combined with the aeration and the capacity chamber which carried out the implant, or VDC to the separate flexibility chamber which filled up each above-mentioned document with the gas in the aeration to three means for realizing this failure of pressure, i.e., the atmospheric pressure power which lets the skin pass, and the thorax is indicated. This pumping chamber receives the blood from a left-ventricle crowning, and the blood which won popularity is sent into the pumping chamber indicated in document besides Frazuer by the main artery across a channel parallel to the left ventricle, and it has a blood channel parallel to the left ventricle in this way.

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EFFECT OF THE INVENTION

[Effect of the Invention]1. The demand over a blood pump device small enough which the implant is thoroughly carried out with related electronic parts, and can avoid fear of the infection relevant to an endermic lead is fulfilled.
2. Even if it is a thing of which chamber gestalt of the separate chamber which connected with the pump using the part or gastight envelope of a pump, the blood pump device which should not need the 2nd chamber for flexibility is provided.
3. The blood pump device which receives the blood in low filling pressure from a main artery base, drives a pump, high-voltage-izes blood all the time rather than it in a distant main artery, and returns the blood which won popularity to an ascending aorta in contrast with a parallel joint passage is provided.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]Therefore, the issue which it is going to solve is fulfilling the demand over a blood pump device small enough which the implant's is thoroughly carried out with related electronic parts, and can avoid fear of the infection relevant to an endermic lead. Other issues which it is going to solve are providing the blood pump device which is a thing of which chamber gestalt of the separate chamber which connected with the pump using the part or gastight envelope of a pump, and should not need the 2nd chamber for that and flexibility. Furthermore it is going to solve, other SUBJECT is providing the blood pump device which drives a pump for the blood which received blood and won popularity, and returns blood as a much high-pressure thing rather than it in a distant main artery under filling pressure low from a main artery base in contrast with a parallel joint passage at an ascending aorta. With the left ventricle, such a connection configuration may be referred to as it is "serial".

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MEANS

[Means for Solving the Problem]A blood pump device according to this invention in which implant is possible may contain pump housing which has pump parts and a drive chamber which stores drive mechanism. Pump parts may be the plate members of flatness or the shape of a glass combinable with pump housing. Drive mechanism may contain an electric servomotor which has a stator, a rotor, and an output shaft. An output shaft is combinable with an eccentric shaft which may have a cam part. a pumping arm which a cam part may be a roll cam and has an end part which follows a cam can be provided -- an omitted portion of a pumping arm -- housing -- a pivot -- it can equip rotatably. a pivot -- an end of a pumping arm attached rotatably contacts a cam surface intermittently, and the surface of an end of a pumping arm acts as a cam follower. The other end of a pumping arm is combinable with a movable plate. A compressive blood chamber which combined an entrance and an exit with the circulatory system can be made to pinch between a glass shaped part and a movable plate. A valve for supporting that arterial blood passes a blood chamber only in one way certainly can be provided in an outlet position of a blood chamber. In this way, if a cam is rotated and a cam rotates, a pumping arm will carry out [center of rotation /, i.e. a center / omitted portion / which was fixed /,] the pivot rotation of the electric servomotor. A movable plate compresses and releases a blood chamber periodically by pivot motion of a pumping arm, and pumping of the blood is carried out through the circulatory system. It is preferred that carry out the implant of the movable plate side of a blood pump device to a position which adjoins a lung, and a movable plate moves, blood faces that pumping is carried out and a lung moves with this movable plate. Therefore, a lung can be used as a flexibility chamber for a blood pump device. After all, the necessity of providing a flexibility chamber independently is lost. It is preferred to combine a reduction gear between an electric servomotor and an eccentric shaft. A reduction gear may have gear array constitution with four planetary gears. A metal bellows member for sealing seals can be provided in the circumference of an omitted

portion of a drive chamber and a pumping arm. A bellows member prevents drive mechanism from carrying out the seal of the drive chamber in the circumference of an end of a pumping arm, and contacting body fluid by that cause. A bellows member carries out the sealing seal of the space, and it provides a means for transmitting movement of a driving assembly, without tearing such a sealing seal.

[0014]Some blood pump devices can surround all with an envelopment bag made from Polymer Division preferably filled up with an isotonic salt water solution, and the parent organization surface which surround an organization can be made to provide. An envelopment bag prevents an organization also from being involved in a movable part of a blood pump device. A position sensing device for determining relative blood volume in a blood chamber can be positioned. Both relative blood volume in a blood chamber can serve as information which displays blood volume and cam positions in a blood chamber. Especially this information can be used in order to control motor speed and to optimize a pump operation, when blood discharge from a blood chamber should be started. The implant of the blood pump device may be carried out in various composition. A standard artificial blood vessel can be used for an entrance and an exit. Exit cannula is joined to a thorax ascending aorta, entrance cannula is joined at a thorax ascending aorta (in series), only one valve is provided in exit cannula, or it can join (in parallel) and an integral-type valve can be provided in each cannula of an entrance and an exit at a crowning of left ventricle (LV).

[0015]The implant of the electronic control object which carried out the sealing seal for making some functions for controlling operation of a blood pump device provide can also be carried out. An ECG lead can be combined with the heart and an electronic control object can be made to supply a signal. Such a signal can be used instancy for ****** in order to control **-SHINGU. The same ECG lead is used, and if required, pacing of a patient's heart can also be carried out. Since many of cardiac insufficiency patients have the high danger of starting ventricular fibrillation (sudden cardiac death), they can also pull out electric ****** / ****** lead from an electronic control object. Electrical energy to this electronic control object can be supplied via endermic energy and a data transmitting system (it is also hereafter called TEDTS). TEDTS can use a hypodermic (secondary) coil which carried out the encapsulation. A hypodermic coil is connected to an electronic control object after all. An external (primary) coil which agrees with a hypodermic coil can be fixed to a patient's skin, energy can be transmitted to an electronic magnetism target at a secondary coil, and an electronic control object can be operated. It is also possible to use such a coil pair doubling object in order to send data in both directions between an electronic control object, and external detection and a program device. Such one system for sending electric power and data endermically is indicated to US,5,630,836,B. A battery of an electronic control object may be charged during the usual TEDTS operation. When external coiling of TEDTS was removed from a patient's

skin, or that was not right and electric power of TEDTS declines, electric power required in order that a battery pack of an electronic control object may operate an in-plant system for several hours can be provided.

[0016]

[Embodiment of the Invention]With reference to Drawings, the blood pump device 10 in which the perfect implant is possible to drawing 7 is illustrated by explaining this invention from drawing 1, It is combined on operation with the component parts 200 relevant to a patient's circulatory system, for example, an electronic control object, (it is also hereafter called EC), the battery pack 210, and TEDTS220. the blood pump device 10 can carry out the implant to which a thorax on either side -- a parallel form -- or it is connectable with the circulatory system under series constitution. The right thorax implant composition for assisting drawing 1 and drawing 5 with the parallel form of another mode in the ventricle is illustrated. The left thorax implant composition for assisting drawing 4 with a parallel form in the ventricle is illustrated. Also in which thorax implant on either side, the implant of the blood pump device 10 can be carried out under the state where blood takes a channel from a left-ventricle crowning to an ascending aorta in the thorax of a human body (or animals other than a human body). The blood pump device 10 can be positioned so that a lung may push the operation side of this blood pump device a little. By arranging in this way, the blood pump device 10 becomes the thing of automatic flexibility which used lung tissue, and the necessity over a separate flexibility chamber is eliminated. A pumping function also relates to a target directly further with a blood flow lead pipe.

[0017]The blood pump device 10 of arbitrary composition can be arranged inside a breast wall in the position of the almost same height as the heart, as shown in drawing 2 and drawing 3. The blood pump device's 10 pressure of the blood chamber 20 will show that the blood chamber 20 comes to be thin by the discharged blood volume. In this way, a lung will act as a flexibility chamber for the blood pump device 10. This brings about the clear profits which excel the blood pump device assembly from the former which needs the artificial chamber which carried out gas charging, in order to obtain flexibility. If time passes, by discharge, gas volume needs to be lost, and it needs to be periodically re-filled up with an artificial chamber after all, and it needs to maintain the capability. It is too large for including a blood pump device assembly in a thorax in a system conventionally [most]. Such conventionally, in a system, blood pump device assemblies are completely different component parts, and if a flexibility chamber has space, the implant of it may be carried out even to somewhere else. Therefore, the airtight tubular terminal area for connecting a flexibility chamber to a blood pump device assembly is provided. The component parts by which the implant is carried out decrease, and there is also little space required for the implant much, and they can be managed with the blood pump device of automatic flexibility. Therefore, this invention is substantial much space

efficiency-like [assembly / from the former / which needs a flexibility chamber separately / blood pump device].

[0018]Much profits can be obtained by obtaining flexibility using the lung space in the thorax. For example, since the pressure in lung space is very close to atmospheric pressure, the ideal situation for being filled up with a pumping chamber is provided, it is one of these and the necessity over a flexibility chamber is eliminated. It cannot be overemphasized that a direction with few parts for a human body which need to carry out the implant is good. The lung is extremely rich in flexibility, and on the whole, it can bear, without receiving or spoiling an adverse effect to a lung function also to some compression and expansion. Unlike an artificial flexibility chamber, the lung does not need to produce "leaking", therefore does not need to be periodically re-filled up with it. And the thorax protects a blood pump device. A blood pump device is the inside of a breast wall, and as shown in drawing 4 in the state of adjoining the heart and contacting a rib, it may be arranged. Interference with a lung function is a minimum grade, and occupation space is efficiently used by that a pumping chamber is flat on the whole.

[0019]As shown in the blood pump device 10 at drawing 7 and drawing 8, it can also attach under series constitution at the circulatory system. The ventricular assist system from the former, i.e., VAD, is typically attached at the circulatory system under a parallel form as shown in drawing 1, drawing 5, and drawing 6, and an entrance conduit receives the blood from the left-ventricle crowning 2 in that case. In such array constitution, blood flows into a blood pump device from a ventricle pars basilaris ossis occipitalis. When it is supposed that the blood channel in the conventional VDA is parallel to the blood channel of the usual left ventricle, therefore the blood pump device of VAD breaks down, these parallel blood channels have a possibility of getting it blocked by a thrombus. In the case of series constitution, if a blood pump device breaks down, a blood channel will become longer than usual, but since blood continues being sent to a blood pump device, a thrombus becomes difficult to happen. Therefore, series constitution is safer as compared with a parallel form, even when a blood pump device breaks down. It replaces with the blood from the left ventricle being sent out from the crowning of the left ventricle in a parallel form, so that that may be right, Usually, since it is sent out to a target through an aortic valve, a possibility of getting a blood flow blocked within a blood pump device at the time of blood pump device failure not only decreases, but the high danger of getting a blood flow blocked within the left ventricle decreases. Other strong points in the case of considering it as series constitution are that what is necessary is just to provide only one valve in the exit pipe of a blood pump device. By contrast, it is necessary to provide one each and a total of two valves to each lead pipe of an entrance and an exit in a parallel form. or [providing such a valve in the inside of a long lead pipe] -- or a part of connector assembly is used. Mechanical or, in any case, the valve of living thing replaceability is used.

However, what is necessary is just to position only one valve in an exit pipe, since the original aortic valve of the heart can act as an inlet valve of a blood pump device in the blood pump device of series constitution.

[0020]The conventional technique for attaching a lead pipe to the circulatory system is illustrated by drawing 12 from drawing 9. A lead pipe is connectable with a blood pump device by suturing using the quick connector which used the coupling frame of spool form or was manufactured beforehand. The coupling frame of spool form covers this coupling frame, and has the design shape which has the artificial blood vessel put firmly on coupling frame by a band or ligation. A quick connector has an end with which it agrees for combining a lead pipe with a blood pump device. The termination of the end of the blood pump device 10 and the end of the condom made from polyurethane is carried out in the position of these connecting parts irrespective of the form of the connecting part to be used.

[0021]The implant technique in series constitution is illustrated by drawing 11 from drawing 9, and it is exposed for the connection with an inflow lead pipe of a thorax ascending aorta. While carrying out the pinch stop of the one segment of an arterial wall using a SATINSUKI (satinski) clamp, the usual artery flow is maintained without blocking. On the occasion of preparation incorporating an inflow lead pipe, the section in which the artery carried out the clamp stop is cut open for a long time. Subsequently, the end of an inflow lead pipe is sutured to the flank of an artery using surgical closure. The clamp of the approaching side is removed and air is extracted from an inflow lead pipe using the hypodermic needle. After carrying out air extraction, the clamp by the side of a distant place is removed. Thereby, the artery separation part or constriction part for sending the blood from the left ventricle in in-series through a blood pump device in an ascending artery at an arterial system is created. In order to connect the lead pipe of series constitution to an artery, junction between ends to a heart bypass can also be used.

[0022]The implant technique in a parallel form is shown in drawing 14 from drawing 12, and it is exposed for cannula inclusion of one segment of a thorax ascending aorta. The pinch stop of the one segment of an arterial wall is carried out using a single SATINSUKI (satinski) clamp, and on the other hand, the usual artery flow is maintained, without blocking. The section in which the artery carried out the clamp stop on the occasion of preparation incorporating cannula is cut open for a long time, it ranks second and the end of cannula is sutured to the flank of an artery using surgical closure. The sutured cannula is used as an exit pipe of a blood pump device. Subsequently, cannula is built into a left-ventricle crowning and this cannula is connected to the entrance conduit of a blood pump device. Since the blood pump device combined by this parallel form has fear of air ****** by having an opening in the left-ventricle crowning, probably the heart bypass for the implant is required for it.

[0023]The quick connector assembly 80 from the former is shown in drawing 15 and drawing

16. The entrance 24 or the exit 22 of the blood chamber 20 is combined with the actuator septum 84. The sleeve 88 for a lock can be attached to the actuator septum 84, and it can be considered as the fixed tip for the quick connecting part of the quick connector assembly 80. The artificial blood vessel 110 is joinable to the base material ring 86. The base material colors 92 surround the base material ring 86, and it may have the two pins 90 for a lock of one. The compression spring 94 can be formed between the base material ring 86 and the base material color 92. The compression spring 94 is compressed between the base material ring 86 and the base material color 92, and is held by the pin 90 for a lock at an appropriate position. The pin 90 for a lock is slidable in the inside of the long hole 98 in the base material ring 86. The O-ring 82 can also be arranged between the base material ring 86 and the base material color 92. The O-ring 82 is held with the base material color 92 at an appropriate position. Another O-ring 82 can be arranged between the base material color 92 and the sleeve 88 for a lock. Thus, the seal of the quick connector assembly 80 may be carried out to body fluid. The actuator septum 84, the entrance conduit 24 or the exit pipe 22, the O-ring 82, and the sleeve 88 for a lock are contained in the actuator side edge part of the quick connector assembly 80. The blood flow lead pipe 110, i.e., an artificial blood vessel, the pin 90 for a lock, the base material color 92, the compression spring 94, and the O-ring 82 are contained in the lead pipe side edge part of the quick connector assembly 80. On the occasion of an assembly, a lead pipe side edge part and an actuator side edge part are brought near, and it lets the pin 90 for a lock pass to the long hole 100 of the sleeve 88 for a lock. Subsequently, each end is advanced, the base material color 92 is rotated clockwise, and the pin 90 for a lock is moved along the passage of the long hole 100 of the sleeve 88 for a lock. If connection is completed, the seal of the inside will be carried out from a human body, and, as it thinks best, a quick connector assembly will be held by the O-ring 82 with the pin 90 for a lock, and the compression spring 94. Please understand that the quick connector assembly in another mode can be used. It is important that a delicate circular connecting part can be sutured surgically, without receiving the physical interference by a pump existing by using a quick connector assembly. The surgeon can continue at the suture which connects a lead pipe with the circulatory system, and can carry a pump quickly using a quick connector assembly.

[0024]The blood chamber 20 is producible from polyurethane of the medicine grade which has elasticity compressibility and living thing stability, for example, polyurethane of form which is indicated to US,5,133,742,B. An one surface pattern may be given so that the organization chart side which extends in the inside for the inner surface in contact with the blood of the blood chamber 20 to form a biological blood contact surface may be provided. A surface pattern may consist of the staple fiber by which orientation was carried out by intersecting perpendicularly with the surface of the blood chamber 20. Such a surface pattern may be indicated to US,751,839,B. The surface encaustic attachment by textiles can promote the

manifestation of biological intima lining. As for intima lining, it is preferred to carry out the distraction of the blood chamber 20 and the artificial blood vessel 110 whole without a stitch. The artificial blood vessel made from Dacron (brand name) is also because the organization which extends inside is made to reveal preferably and the biological surface may be produced inside an artificial blood vessel by that cause. As the blood chamber 20, on the whole, has flow through type design shape and a vortex or a flow stagnation zone is minimized, change of a cross-section area may be the minimum.

[0025]It may be formed by any of each in-series or parallel circulation combining form type it chooses again they are by whether the blood chamber 20 positions the blood pump device 10 to which [of the thorax] side by having rhombus shape substantially in itself with various composition. For example, some different composition is illustrated by drawing 19 from drawing 17. The composition for connecting a blood chamber with thorax right-hand side in parallel form is illustrated by drawing 17. In the steel things connected with thorax left-hand side in parallel, a blood chamber makes what is shown in drawing 17, and a mirror image. In order to carry out a series connection to thorax right-hand side, the blood chamber 20 can become a thing of composition of positioning substantially [mutual] an entrance and an exit as shown in drawing 19 in an opposite hand. However, the blood chamber 20 may be formed in non-flow through type "blind porch" composition which is illustrated to drawing 18 in another mode which carried out the series connection to thorax right-hand side. Irrespective of specific composition, the material composition of the blood chamber 20 is the same, and is acquired. That and the blood chamber 20 may be produced from polyurethane of the medicine grade referred to previously with which composition.

[0026]The blood pump device which follows this invention with reference to drawing 26 from drawing 20 is shown, and the pump housing 13 has the glass-like portion 15, the drive chamber 18, the blood chamber 20, and drive mechanism. The pumping arm 33 and the movable plate 28 are contained in drive mechanism. As for the pump housing 13, the pumping arm 33, and the movable plate 28, it is preferred to constitute all from titanium. A blood chamber can be positioned in the glass-like portion 15 of the pump housing 13. The glass-like portion 15 may have the opening 16 for the entrance 22 of the blood chamber 20, and the exit 24. Although the glass-like portion 15 is shown in the shape of a glass by a diagram, a bottom plate flat on the whole can also be used. Except for the movable plate 28 having surface area smaller desirable a little than the surface of the blood chamber 20 where this movable plate 28 is pushed, it may have the blood chamber 20 and shape corresponding on the whole. It is preferred to face to carry out the implant of the blood pump device 10 to a patient, and to position so that at least some movable plates of the blood pump device 10 may adjoin at least a part of a patient's lung 5 and it may be positioned. In order that the movable plate 28 may carry out pumping of the blood by doing so, the lung 5 can be faced moving so that it may

illustrate from drawing 2 to drawing 3, and it can be moved now with the movable plate 28. After all, a changed part of the capacity of the blood pump device 10 is compensated with a lung acting as a flexibility chamber for this blood pump device 10.

[0027]As for the edge of the movable plate 28, as shown in drawing 21 and drawing 23 thru/or drawing 24, when the blood chamber 20 is compressed, in order to keep stress from concentrating on the edge position of the movable plate 28, it is preferred to have the curvilinear shape which separates from the blood chamber 20. The blood chamber 20 and the size shape of the movable plate 28 are faced the blood chamber 20 being pressurized and being compressed, and they can be optimized so that the bending stress and hoop tension which are produced into the flexible portion of the blood chamber 20 may become the minimum. The blood chamber 20 should be repeatedly deformable and it should be possible to return to the state before modification qualitative moreover in addition as a matter of fact. The bending stress can cope with it, when the blood chamber 20 chooses carefully the proper wall thickness which can be equal to total compression. As for the entrance 22 and the exit 24 of the blood chamber 20, it is preferred to position in the flat surface of the greatest projection part of the blood chamber 20. After all, the blood chamber 20 can become a thing of the thinnest outline.

[0028]Theoretically, in order to optimize the blood chamber 20, the necessity of taking many complicated phenomena into consideration may arise. The deviated amount which the blood chamber 20 receives in the 1st first is large as shown in drawing 23 and drawing 24, but it is being unable to explain this phenomenon by the principle of the simple intensity of material. It is because the ingredient of the action of the material showing big modification and deflection is omitted for simplification. It is the cause for which the point said that a "schoolbook" answer is a thing to easy shape and ingredient also causes complication to the specific three-dimensional shape of the predetermined blood chamber 20 being explained. Are the characteristic that Polymer Division used for the 2nd by this invention has the nonlinear relation between stress and a strain having, and to the 3rd. It is a point which the blood chamber 20 says that itself is a complicated contact phenomenon and the local deformation for bending around the edge of the movable plate 28 is a thing directly in connection with the shape of the movable plate 28, or the thickness of the blood chamber 20. One practical method of evaluating the blood chamber 20 uses finite-element analysis, taking such a factor into consideration. In this solution, the ingredient which poses a problem is decomposed into a small and simple portion (element) all the time. Subsequently, each element is solved simultaneously, it faces formulating an element, and complexity is explained. To the problem mentioned above, a remarkable computer resource and computation time are needed.

[0029]The blood chamber 20 of this invention receives simultaneously the strain which bends during operation of the blood pump device 10, and originates in a pressure. As stated

previously, such bending is involved in the shape of the edge of the movable plate 28, and the thickness of the blood chamber 20. It is decided by length S_F of the portion which also has a strain produced by blood pumping in the state of receiving not only the thickness of the blood chamber 20 but pressure load. In short, the pressure load added to the blood chamber 20 becomes large, so that this length S_F becomes long. If the blood chamber 20 is thickened, the amount of strains resulting from a pressure will decrease, but the amount of strains at the time of the blood chamber 20 bending around the movable plate 28 increases. In this way, bending and making each strain by a pressure balance is included in a design problem. Subsequently, it is necessary to determine blood chamber 20 shape of bringing about the best performance, by changing the edge shape of the movable plate 28, partial length S_F of the blood chamber 20, and the chamber width in length S_F.

[0030]Typically, the component parts made from Polymer Division have the design shape which maintains the predetermined strain level over the life of these component parts. Therefore, it may be necessary to get to know the maximum amount of strains permitted to a predetermined material and load frequency. According to the conventional research, it was shown that a maximum of 15% of strain may be permitted to 2 million cycles to the polyurethane used for this invention. After all, this strain level can be used as design allowable maximum stress deformation of the component parts made from polyurethane of this invention.

[0031]With reference to drawing 25 and drawing 26, drive mechanism may contain preferably the servo motor 56 of an electric type connected with the reduction gear 70 for rotating the eccentric shaft 47. The eccentric shaft 47 drives the pumping arm 33 and the movable plate 28, and can carry out pumping of the blood. The stator portion 58 and the rotor portion 60 are contained in the servo motor 56. ** arrival of the stator portion 58 is carried out to housing, and the rotor portion 60 may contain the output shaft 62 for rotating the eccentric shaft 47 and generating a pumping action. the servo motor 56 -- a power supply -- and -- or the electric power coupling 79 for connecting with EC200 can be formed. The servo motor 56 may have various sizes or aspect ratios. As for the servo motor 56, what can carry out continuous rotation by about 2,000 to 3,000 RPM is preferred. Sierracin/Magnedyne of California Carlsbad can manufacture the servo motor 56, for example. The servo motor 56 carries out pumping of the blood at speed of per minute 120 beats, and, as for the cylinder capacity of a blood pump device, it is preferred that it is 60-80 ml. In addition, a blood pump device resists the pressure in the range of human being's arterial pressure power in the blood in cylinder capacity, and should move blood. In the case of a cardiac insufficiency patient, generally, such arterial pressure power ranges are about 160 mmHg(s) in the maximum. Such a standard can be used and the design of blood pump device 10 blood chamber 20, pumping arm 33, servo motor 56,

and reduction gear 70 and other component parts can be optimized. the calorific value which silence-operates the servo motor 56 and the reduction gear 70, and may be received -- and it should be preferably designed also for the long operation life in the maintenance free situation for at least five years.

[0032]As for the reduction gear 70, it is preferred to join together between the output shaft 62 and the eccentric shaft 47. As for the reduction gear 70, it is preferred that it is a planetary-gear-type reduction gear which changes rotational movement of the servo motor 56 into the number of cycles between per minute about 80 and 120 as gear ratio best shown in drawing 26 of 25:1. The speed of the servo motor 56 and the ratio of the reduction gear 70 can be chosen so that energy efficiency may be attained and the compactest drive mechanism may be provided. One rotation of the output shaft of the reduction gear 70 operates one process of blood pump devices 10, and this distance operation arises in the range which is per minute about 60 to 120 cycle. Although some planetary-gear type reduction gears which can carry out commercial acquisition are various, in order to reconcile minimization of size shape, and maximization of efficiency, it is preferred to use the thing of an order design. The planetary-gear type reduction gear 70 may be a thing of 3 gear differential (it is also hereafter called TGD) mold as shown in drawing 26. Although the gear type reduction gear of other forms can be used, TGD is preferred from especially small being energy efficiency-like. Inside flywheel starter gear may be contained in the reduction gear 70 of this form. It is known that inside flywheel starter gear have few slides at the time of engagement, and the contact ratio for transmitting load to a target more gradually is high. TGD is long-life, and more efficient than the reduction gear of other forms, and the load support capacity to a prescribed dimension is not only large, but it a low noise. Rather than a more general 4 gear differential type thing, there are few a gears, therefore they can miniaturize TGD. As for a planetary gear, it is preferred to use four pieces. A load passage will be 4 times by doing so, and it enables the number of planetary gears to miniaturize the whole shape all the time rather than fewer things.

[0033]The output shaft of the reduction gear 70 is combinable with the eccentric shaft 47. The eccentric shaft 47 may have the input part 48 which attached the flywheel-starter-gear portion 68 which may be driven with the reduction gear 70 so that it may be best shown in drawing 25. The pumping arm 33 contacts in the form where it rides on the circumference of an end of the eccentric shaft 47. After all, although the eccentric shaft 47 drives the pumping arm 33 in a pumping process, the inside of the return process [it fills up with the blood chamber 20] of a between carries out the free movement of the pumping arm 33, without being restrained. The cam which is the roll bearing 52 and is obtained is attached to the end of the eccentric shaft 47, and the end of the pumping arm 33 follows for this cam. The center of rotation of the eccentric shaft 47 is shown as C_{axis}.

[0034]As for the pumping arm 33, it is preferred to carry out orientation into the flat surface

which intersects perpendicularly with the axis of rotation of a servo motor and a reduction gear. the omitted portion of the pumping arm 33 -- a pivot -- the bearing 43 can be formed in the position of center-of-rotation C_{arm} of the portion attached rotatably. It is preferred to use the sleeve made from Polymer Division which low abrasiveness does not illustrate by non-corrosiveness as a bearing for combining the pumping arm 33 with the movable plate 28. Materials desirable for this connecting part are PPS sleeve material and 316 stainless steel. The end of the side in contact with the cam surface of the pumping arm 33 operates as the cam follower 45. The pumping arm 33 is periodically rocked, as best shown in drawing 22 focusing on the center-of-rotation C_{arm}, and periodic pumping of the blood chamber 20 is attained as the cam 52 rotates on an eccentric shaft. The ratio of the distance from the center of rotation of the pumping arm 33 which carries out pivot motion to each end is expressed with drawing 21 as D_1 and D_2, and determines possible lever ratio in the predetermined geometrical form of the pumping arm 33. As for distance D_1 from the center of rotation of the pumping arm 33 to the movable plate 28, what is larger than the distance to the surface of the cam 52 is preferred. The torque conditions for the eccentric shaft 47 can become the lever ratio of a pivot arm with what also has a quite big twist. However, by that cause, the hardware for energy conversion (a servo motor, a reduction gear, a cam) can be brought close to center-of-rotation C_{axis} of the eccentric shaft 47, and can be positioned now, and it enables much more miniaturization of drive mechanism. It is preferred to form the position sensing device 39 in the position which adjoins the omitted portion of the pumping arm 33. The position sensing device 39 may be an eddy current sensor for detecting the position change of the pumping arm 33, for example. The relative capacitor of the blood in the blood chamber 20 can be determined from the position change of the pumping arm 33, and the position of the eccentric shaft 47 or the cam 52 can be determined.

[0035]The movable plate 28 may have the central joint point 29 which can serve as an installation part of the end 41 of the pumping arm 33. It can pierce through punching in a movable plate, and punching of the end 41 of the pumping arm 33, and the pin 30 can be arranged. Thereby, the pin 30 hinges the pumping arm 33 on the movable plate 28. As for the pumping arm 33, it is preferred to rock the inside of the flat surface which intersects perpendicularly with the movable plate 28. By having hinged the pumping arm 33, orientation of the movable plate 28 may be carried out in the direction that the strain of the blood chamber 20 may be minimized during process operation, in itself. As for center-of-rotation C_{arm} of the pumping arm 33, providing in a drive chamber is preferred.

[0036]Since the surface of the cam 52 contacts the pumping arm 33 intermittently, the period only until between the compression phases of cam rotation operates and blood is [drive

mechanism] full of the blood chamber 20 even in such a case operates. In this way, the blood pump device 10 carries out pumping only of the blood with which the blood chamber 20 was filled up between the retreat phases of a cam surface. Thus, the movable plate 28 is separated from a servo motor, while the blood chamber 20 is full, and moreover, in addition, it moves up and down continuously, without carrying out pumping of the blood chamber 20. the case where pumping of the blood chamber 20 with which this is not filled thoroughly is carried out -- the film of the blood chamber 20 -- ** -- better or ******** occurs -- and -- or the pressure of the left ventricle is prevented from declining superfluously.

[0037]The sealing seal of the center-of-rotation C_{arm} of the pumping arm 33 and the drive chamber 18 can be covered and carried out, and the SHIRUBE rose 38 for keeping away body fluid from drive mechanism can be formed preferably. The end caps 36 and 37 can be established in which end of the SHIRUBE rose 38. The end cap 37 of front sides has the opening by which the seal was carried out to the circumference of the pumping arm 33, and the bellows portion 35 leads to the drive chamber 18 through this opening. As for the SHIRUBE rose 38, producing from titanium is preferred. The SHIRUBE rose 38 is an important characterizing portion from this enabling the component parts for energy conversion to have lubrication fluid of abiosis compatibility, and corrosive hard steel being shielded from the salt water (saline) environment of a human body. By forming the SHIRUBE rose 38, a possibility that a gear, a bearing, and a motor may corrode can decrease greatly. The corrosion of such parts may be generated when body fluid diffuses in the drive chamber 18. Although it seals the drive chamber 18, if the transfer to the movable plate 28 is possible for the SHIRUBE rose 38, in addition, it closes the mechanical energy of the servo motor 56. The bearing made from the hardened steel which operates about five years or more under protection lubricous environment, and a gear and other parts can be used now by the sealing seal of the motor drive assembly being carried out. It is desirable to use the parts made from hardened steel from the ability for it to be efficient and transmit the power energy inputted into an electric motor to blood work by the bearing made from hardened steel, or the rolling friction of another gear and motor driving section article. By approaching center-of-rotation C_{axis}, and positioning the hardware for energy conversion (a servo motor, a reduction gear, a cam), it becomes possible to miniaturize the whole drive mechanism more, and it minimizes movement induced by the SHIRUBE rose. After all, the sealing seal of the drive mechanism can be carried out now more practical.

[0038]By forming the envelopment bag 105 made from Polymer Division in the circumference of the blood pump device 10, as shown in drawing 2 and 3, it is preferred to provide the surface which adapts itself to the organization of the patient who surround the blood pump device 10. It is preferred that this envelopment bag 105 is surrounded with the pumping arm 33 and the movable plate 28 at least, and an organization is made not to be involved in in the

operating space of the pumping arm 33. elastic deformation is free for the envelopment bag 105, it is boiled under a state which differential pressure does not produce the upper part and around the envelopment bag 105, and moves with the movable plate 28. The envelopment bag 105 prevents and carries out growth of the organization towards in the field of this envelopment bag 105, and it prevents beforehand connection of the pumping arm 33 to such an organization. The blood pump device 10 whole can also be stored to envelopment bag 105 inside, if required.

[0039]Even if it is which parallel or in-series blood flow composition, the blood pump device 10 can be operated without making it synchronize synchronizing with the heart 1. In synchronized operation, typically, the blood pump device 10 discharges blood, whenever the left ventricle contracts. The timing of blood discharge of the blood pump device 10 is controlled by detecting the degree (QRS) of electrical activity of the heart in case the left ventricle discharges blood (contraction). When this degree of electrical activity is detected, the blood pump device 10 can discharge blood after the time delay preset immediately. However, as for blood discharge of the blood pump device 10, it is preferred to be carried out after the left ventricle finishes blood discharge. In asynchronous operation, the blood pump device 10 often discharges blood regardless of QRS. the time delay back by which it was programmed for example, after QRS signal detection in alignment mode as for the blood pump device 10 -- or it contracts after the stimulative pacing pulse of the electronic control body which carried out the implant. In asynchronous mode, when, as for pumping, the position sensing device 39 detects that the blood chamber changed into the fullness state mostly, the electronic control body 200 may begin, for example.

[0040]In asynchronous mode, it is desirable to operate the servo motor 56 at a comparatively fixed speed, and to minimize the reaction force and power loss relevant to acceleration and deceleration of a gyrating mass. As for the speed of the servo motor 56, when the blood chamber 20 starts each blood elimination phase, it is ideal to adjust so that it may be mostly full. If revolving speed is too slow, the blood chamber 20 will expand before the start of a blood elimination phase, and will restrict the inflow of blood. This has a possibility of heightening the pressure of the left ventricle superfluously. On the contrary, when revolving speed is too quick, there is too little blood volume discharged from the blood chamber 20, in order to flush the inner surface of the blood chamber 20 appropriately in each cycle. When revolving speed is too quick, the amount of power losses by friction or viscosity becomes large superfluously.

[0041]It is the blood chamber 20 at the start time of each elimination phase, and one means for carrying out optimum control of the motor speed so that it may be mostly full is illustrated by drawing 27. The curve 100 expresses cycle movement of the cam of the output shaft of a reduction gear. In the position shown by the line 102, the cam 52 is drawn thoroughly and the pumping arm 33 is in free floating at the time of the peak filling position being filled up with the

blood chamber 20. In the position of the line 103, 180 degrees rotates and the cam 52 compresses the blood chamber 20 into the maximum via the pumping arm 33. The blood chamber 20 is freely full of the blood sent from the left ventricle between the blood inflow phases shown by the line 104. In the blood elimination phase shown by the line 105, the blood chamber 20 is compressed by the operation of a cam and the pumping arm 33, and the blood from the blood chamber 20 is sent out to an artery via a blowdown valve. The lines 106, 107, and 108 show the relative capacitor of the blood within the presumed output value 20 from the position sensing device 39 which detects the position of the pumping arm 33, i.e., a blood chamber. Before starting the blood elimination phase 105, it fills up with the blood chamber 20 when the revolving speed of a motor is too much slow thoroughly, and the line 106 expresses the situation of coming to restrain movement of the pumping arm 33, only when the cam 52 is the position 109. When the line 108 has too quick the revolving speed of a motor, at the start time of the blood elimination phase 105, the blood chamber 20 accepts it selectively, is full, and shows in it the situation where the cam 52 comes to restrain movement of the pumping arm 33 only at the time of the position 111. Motor revolving speed is adjusted properly, it is the blood chamber 20 at the start time of the blood elimination phase 105, and is filled with the line 107 nearly thoroughly, and the cam 52 is the position 110 immediately after the start of the blood elimination phase 105, and the situation of coming to restrain movement of the pumping arm 33 is illustrated. The contact position of the cam / pumping arm expressed with the numbers 109, 110, and 111 of drawing 27, respectively is easily detectable because the differential coefficient of the beginning of the output of the position sensing device 39 becomes negative. The revolving speed of a motor can be adjusted to optimum by raising rotation of a motor, when the contact detected in the detection value of the contact position of a cam and a pumping arm as compared with the ideal contact position 110 is too early, and slowing down motor revolving speed, when contact is too slow.

[0042]In the synchronous mode, the blood chamber 20 synchronizes with a QRS signal, receives the blood between the contraction phases of the left ventricle, and, subsequently to between the expansion phases of the left ventricle, discharges blood. The epicardium from the former or endocardium ECG detection, and a pacing lead can be provided between a patient and the electronic control body (EC) 200, a cardiac cycle can be supervised, and operation of a blood pump device can be synchronized correctly. The time between the output pulses of the pacer between the detected compound QRS signals is used, and the revolving speed of a motor is controlled so that a cam and a pumping arm end one perfect cycle for every cardiac cycle. The phase to which the motor position about the detected heart cycle relates is adjusted so that the blood elimination phase of the blood chamber 20 may be started, when the abbreviated half of the heart cycle detected when the left ventricle begins to have expanded is passed.

[0043]A defibrillation electrode is provided as 1 component parts of an in-plant system, and it is controllable by EC200 in order to send the therapy shock for irregular **** or the defibrillation. The battery pack which carried out the implant can also use a part of in-plant system, and by the time it is re-filled up using this battery pack at the time of necessity, a blood pump device can be operated for several hours. Usually, the electric power to an in-plant system can be obtained through endermic energy and data transmission (TEDT). The battery pack which carried out the implant and in which re-restoration is possible can provide the electric power for an in-plant system, when it may re-fill up using this TEDT or the electric power supply by TEDT is not performed.

[0044]An electronic control object manages operation of a motor driving body based on the signal received through a pumping arm position sensing device, and arbitrary ECG detection / leads for pacing. the rate response heart rate control for optimizing a CHF patient's cardioassist -- and -- or the physiological sensor for providing control in an AV sequence pacemaker form is incorporable. many of such patients are afflicted by the insufficient condition of the chronotropism -- a rate response ---like -- and -- or AV pacing sequence control may be needed. An ECG electric wire is combinable with an electronic control object via a terminal block. A terminal block can be used also as a connector for a defibrillation therapy electric wire. An electronic control body is operated by a TEDTS subsystem or the electric power supplied with an internal battery pack when the electric power of a TEDTS subsystem declines. A TEDTS subsystem comprises a belt for holding two coils which positioned one side in hypodermic and with which it positioned another side in the outside of the body, an external battery pack, the battery pack of this outside of the body, and a coil to a patient's drum section.

[0045]Another feature of a blood pump device is changed into hemodynamic energy for mechanical energy to attain pumping of blood. As for a step number fundamentally, required in order to transform the electrical energy of a servo motor into the energy for blood work, minimizing generally is desirable. There is inefficiency which produces the loss for every conversion stage in each of energy conversion. In addition to minimizing an energy conversion step number, the efficiency of each conversion stage must be maximized.

[0046]The flow diagram of drawing 28 shows the energy use and efficiency in each of a blood pump device and related system configuration parts. As argued previously, there is efficiency relevant to the stage in each energy transfer stage. If it explains in detail, 3.15-W electric power will be supplied to the motor 325 from the internal electronics 320. Although the 1.57-W electric power which should be sent to the circulatory system 350 remains in the pumping arm 33, the blood chamber 20, and arbitrary heart valves after letting an energy converter pass, this means that conversion efficiency is 45%. Considering that it of most devices which can compete is 10 to 25% of range, this value can be said to be high for a blood pump device. It is

thought that what is depended on using the mechanical constitution parts which are not sliding frictions and probably produce energy loss by rolling friction has conversion efficiency higher than usual. The energy of the reduction gear 330 mainly produces a loss by power loss by friction at a bearing. Similarly, power is lost through a bearing also with a cam / pumping arm 335. Sealing seal-ization of the energy converting device is bearing the important role on efficient-izing. Hardened steel or steel "for bearing" which will corrode energy conversion device hardware under the salt water environment of a human body by being isolated from a patient's body can be used now. The component parts created from such a material have good endurance typically to the consumption caused by rolling friction.

[Translation done.]

* NOTICES *

1.This document has been translated by computer. So the translation may not reflect the original precisely.
2.**** shows the word which can not be translated.
3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]
[Drawing 1]It is a fluoroscopy perspective view showing the blood pump device which carried out multiple connection into the right thorax.
[Drawing 2]It is a fragmentary sectional view in the axial direction which shows a patient's thorax in the position shown in drawing 1, and the blood pump device between lungs.
[Drawing 3]It is a fragmentary sectional view in the axial direction of the blood pump device of drawing 2 which illustrates the situation where a lung acts as a flexibility chamber for a blood pump device.
[Drawing 4]It is a section top view of the blood pump device of drawing 1.
[Drawing 5]It is a fluoroscopy perspective view showing the blood pump device which carried out multiple connection into the left thorax.
[Drawing 6]It is a fluoroscopy perspective view in another mode of the blood pump device which carried out multiple connection into the right thorax.
[Drawing 7]It is a fluoroscopy perspective view showing the blood pump device which carried out the series connection into the left thorax.
[Drawing 8]It is a fluoroscopy perspective view showing the blood pump device which carried out the series connection into the right thorax.
[Drawing 9]It is a fragmentary perspective view which illustrates the inclusion situation of an arterial blood pipe.
[Drawing 10]It is a fragmentary perspective view which illustrates the inclusion situation of an arterial blood pipe.
[Drawing 11]It is a fragmentary perspective view which illustrates the inclusion situation of an arterial blood pipe.
[Drawing 12]It is a fragmentary perspective view which illustrates the inclusion situation of an arterial blood pipe and a left-ventricle tip part blood vessel.

[Drawing 13]It is a fragmentary perspective view which illustrates the inclusion situation of an arterial blood pipe and a left-ventricle tip part blood vessel.

[Drawing 14]It is a fragmentary perspective view which illustrates the inclusion situation of an arterial blood pipe and a left-ventricle tip part blood vessel.

[Drawing 15]It is a partial side cross figure of a quick connector.

[Drawing 16]It is the side cross figure in which the quick connector of drawing 15 carried out partial ****.

[Drawing 17]It is a perspective view of the blood chamber composition made from Polymer Division.

[Drawing 18]It is a perspective view of another blood chamber composition made from Polymer Division.

[Drawing 19]It is a perspective view of another blood chamber composition made from Polymer Division.

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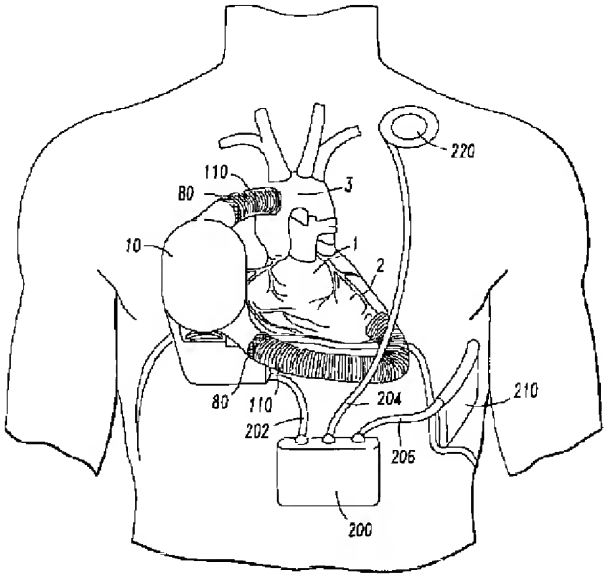
(54)【発明の名称】　単室血液ポンプ装置

(57)【要約】

【課題】　関連する電子部品と共に完全にインプラントされ、経皮的な導線に関連する感染の恐れを回避することのできる、十分に小型の血液ポンプ装置に対する需要を満たすことである。

【解決手段】　血液ポンプ装置１０は人体の胸部内に、血液が左心室頂部から上行大動脈へと流路を取る状態下にインプラントすることができる。血液ポンプ装置１０は、肺がこの血液ポンプ装置の動作側を若干押すように位置決めすることができる。このように配置することにより、血液ポンプ装置１０は肺組織を用いた自動たわみ性のものとなり、別個のたわみ性チャンバに対する必要性が排除される。



【特許請求の範囲】
【請求項１】　患者の循環系に血液を供給するために患者にインプラントすることのできる血液ポンプ装置であって、
a.　駆動チャンバを有するポンプハウジングと、
b.　ポンプハウジングに結合したベース部と、
c.　ベース部に隣り合う側部を有し、循環系にそれぞれ結合し得る入口及び出口を有する圧縮性の血液チャンバと、
d.　血液チャンバの、ベース部とは反対側の側部に隣り合う可動プレートと、
e.　可動プレートにピボット運動自在に結合した第１の端部を有するアームと、
f.　駆動チャンバ内に収納された駆動機構にして、アームの第２の端部に結合され、アームを、可動プレートとベース部との間で血液チャンバを圧縮することにより血液を循環系を通してポンピングさせるために運転される駆動機構と、
を含み、
g.　血液ポンプ装置が、可動プレートの少なくとも一部分を肺の一部分に隣り合わせてインプラントした場合、血液ポンピングに際して肺が可動プレートと共に移動し、血液ポンプ装置内の容積変化が肺によって補償されるようになっている血液ポンプ装置。
【請求項２】　駆動機構が、
a.　偏心軸と、
b.　偏心軸の端部により可動である、アームの第２の端部と、
c.　駆動チャンバ内に収納されたモータにして、偏心軸の該モータと相対する端部に結合された出力軸を有し、出力軸が偏心軸を回転させるとアームがピボット運動しそれにより、可動プレートが血液を循環系を通してポンピングするモータとを更に含んでいる請求項１の血液ポンプ装置。
【請求項３】　アームの第２の端部が偏心軸の端部周囲と接触し、偏心軸が、ポンピング行程中にはアームを駆動し、戻り行程中にはアームの運動を拘束しない請求項２の血液ポンプ装置。
【請求項４】　偏心軸の端部に取り付けたロールベアリングがアームの第２の端部と偏心軸とを仲介し、アームがロールベアリングと接触する請求項３の血液ポンプ装置。
【請求項５】　モータの出力軸と偏心軸の端部との中間位置に結合した減速装置を更に含んでいる請求項２の血液ポンプ装置。
【請求項６】　減速装置がプラネタリーギヤ式の減速装置を含んでいる請求項５の血液ポンプ装置。
【請求項７】　プラネタリーギヤ式の減速装置が３ギヤ差動形式の減速装置を含んでいる請求項６の血液ポンプ装置。
【請求項８】　プラネタリーギヤ式の減速装置が内部リングギヤを更に含んでいる請求項７の血液ポンプ装置。
【請求項９】　プラネタリーギヤ式の減速装置が４つのプラネタリーギヤを含んでいる請求項８の血液ポンプ装置。
【請求項１０】　偏心軸の回転軸線と直交する平面にアームを取り付けた請求項２の血液ポンプ装置。
【請求項１１】　アームの位置変化を検出し、血液チャンバ内の血液量及び偏心軸位置の少なくとも何れかを決定するための位置センサが駆動チャンバ内に配置される請求項１の血液ポンプ装置。
【請求項１２】　位置センサが、アームの角度変化を検出するためにアームの中間位置に隣り合って配設される請求項１１の血液ポンプ装置。
【請求項１３】　位置センサが渦電流センサを含んでいる請求項１２の血液ポンプ装置。
【請求項１４】　駆動チャンバの端部及びアームの第２の端部の周囲をシールし、アームのピボット運動を許容する一方で体液が駆動チャンバに侵入するのを防止するベローズ部材を更に含んでいる請求項１の血液ポンプ装置。
【請求項１５】　ベローズ部材が密封シールされる請求項１２の血液ポンプ装置。
【請求項１６】　駆動機構に作動上結合され且つ駆動機構を制御するためのインプラント自在の電子制御体を更に含んでいる請求項１の血液ポンプ装置。
【請求項１７】　血液ポンプ装置を包囲し且つ血液チャンバの少なくとも入口及び出口のためのシール自在の開口を有する包囲袋にして、組織になじむ表面を提供し且つ組織が血液ポンプ装置の可動部分間に巻込まれないようにする包囲袋を更に含んでいる請求項１の血液ポンプ装置。
【請求項１８】　包囲袋が、包囲袋の周囲に圧力差を生じないように変形自在である請求項１７の血液ポンプ装置。
【請求項１９】　圧縮性の血液チャンバにして、生物学的な脈管内膜ライニングの発現を促す表面模様を施した内側表面を有する圧縮性の血液チャンバを更に含んでいる請求項１の血液ポンプ装置。
【請求項２０】　患者の循環系に血液を供給するために患者にインプラントすることのできる血液ポンプ装置であって、
a.　駆動部分及びポンプ部分を有するポンプハウジングと、
b.　ポンプ部分に配設した圧縮性の血液チャンバにして、循環系に各々接続自在の入口及び出口を有する圧縮性の血液チャンバと、
c.　血液チャンバを血液ポンプ装置に対して圧縮するために血液チャンバの少なくとも一方の側に隣り合って位置付けられる少なくとも１つの可動プレートと、

d.　第１の端部及び中間部分を有する少なくとも１本のアームにして、前記第１の端部が可動プレートにピボット運動自在に結合され、中間部分がポンプハウジングにピボット運動自在に結合されるアームと、
e.　偏心軸と、
f.　偏心軸の端部により可動である、アームの第２の端部と、
g.　駆動チャンバ内に収納したモータにして、偏心軸の該モータと相対する端部に結合された出力軸を有し、出力軸が偏心軸を回転させるとアームがピボット運動しそれにより、可動プレートが血液を循環系を通してポンピングするモータとを更に含んでいる血液ポンプ装置。
【請求項２１】　アームの第２の端部が偏心軸の端部周囲と接触し、偏心軸が、ポンピング行程中に前記アームを駆動し、戻り行程中にはアームの運動を拘束しないようになっている請求項２０の血液ポンプ装置。
【請求項２２】　偏心軸の、アームと接触する端部に取り付けたロールベアリングを更に含む請求項２１の血液ポンプ装置。
【請求項２３】　モータの出力軸と、該出力軸を取り付けた偏心軸の端部との中間位置に結合した減速装置を更に含む請求項２０の血液ポンプ装置。
【請求項２４】　減速装置がプラネタリーギヤ配列構成を含んでいる請求項２３の血液ポンプ装置。
【請求項２５】　プラネタリーギヤ式の減速装置が、３ギヤ差動形式の減速装置を含んでいる請求項２４の血液ポンプ装置。
【請求項２６】　減速装置が内側リングギヤを更に含んでいる請求項２５の血液ポンプ装置。
【請求項２７】　プラネタリーギヤ式の減速装置が４つのプラネタリーギヤを含んでいる請求項２６の血液ポンプ装置。
【請求項２８】　アームが、偏心軸の回転軸線と直交する平面内に取り付けられる請求項２０の血液ポンプ装置。
【請求項２９】　アームの位置変化を検出し、血液チャンバ内の血液容量及び偏心軸位置の少なくとも一方を決定するために駆動チャンバ内に配設された位置センサを更に含んでいる請求項２０の血液ポンプ装置。
【請求項３０】　アームの中間位置に隣り合って配設され、アームの角度変化を検出する位置センサを更に含んでいる請求項２９の血液ポンプ装置。
【請求項３１】　位置センサが渦電流センサを含む請求項３０の血液ポンプ装置。
【請求項３２】　可動プレートの少なくとも一部分を肺の一部分に隣り合わせる状態で血液ポンプ装置をインプラントした場合、血液ポンピングに際して肺が可動プレートと共に移動しそれにより、血液ポンプ装置の容積変化分が肺によって補償される請求項２０の血液ポンプ装置。
【請求項３３】　駆動チャンバの端部及びアームの第２の端部の周囲をシールするベローズ部材にして、アームのピボット運動を許容する一方で体液が駆動チャンバに侵入するのを防止するベローズ部材を更に含んでいる請求項３０の血液ポンプ装置。
【請求項３４】　ベローズ部材が密封シールされる請求項３３の血液ポンプ装置。
【請求項３５】　駆動機構に作動上結合され且つ駆動機構を制御するためのインプラント自在の電子制御体を更に含んでいる請求項２０の血液ポンプ装置。
【請求項３６】　血液ポンプ装置を包囲し且つ血液チャンバの、少なくとも入口及び出口のためのシール自在の開口を有する包囲袋にして、組織になじむ表面を提供し且つ組織が血液ポンプ装置の可動部分間に巻き込まれないようにする包囲袋を更に含んでいる請求項２０の血液ポンプ装置。
【請求項３７】　包囲袋が、該包囲袋の周囲に圧力差を生じないように変形自在である請求項３６の血液ポンプ装置。
【請求項３８】　圧縮性の血液チャンバにして、生物学的な脈管内膜ライニングの発現を促すための表面模様を施した内側表面を有する圧縮性の血液チャンバを更に含んでいる請求項２０の血液ポンプ装置。
【請求項３９】　患者の循環系に血液を供給するために患者にインプラントすることのできる血液ポンプ装置であって、
a.　駆動部分及びポンプ部分を有するポンプハウジングと、
b.　ポンプ部分に配設した圧縮性の血液チャンバにして、循環系に各々接続自在の入口及び出口を有する圧縮性の血液チャンバと、
c.　血液チャンバを血液ポンプ装置に対して圧縮するために血液チャンバの少なくとも一方の側に隣り合って位置付けられる少なくとも１つの可動プレートと、
d.　第１の端部及び中間部分を有する少なくとも１本のアームにして、前記第１の端部が可動プレートにピボット運動自在に結合され、中間部分がポンプハウジングにピボット運動自在に結合されているアームと、
e.　駆動チャンバ内に収納されアームの第２の端部に結合された駆動機構にして、アームを前記中間部分を中心としてピボット運動させることにより、可動プレートをして血液チャンバを圧縮せしめ、血液を循環系を通してポンピングさせる駆動機構と、
f.　駆動チャンバの端部及びアームの第２の端部の周囲をシールするベローズ部材にして、アームのピボット運動を許容する一方で体液が駆動チャンバに侵入するのを防止するベローズ部材と、
含む血液ポンプ装置。
【請求項４０】　ベローズ部材が密封シールされる請求項３９の血液ポンプ装置。

【請求項４１】　駆動機構が、
a.　偏心軸と、
b.　偏心軸の端部により可動である、アームの第２の端部と、
c.　駆動チャンバ内に収納したモータにして、偏心軸の相該モータと対する端部に結合された出力軸を有し、該出力軸が偏心軸を回転させるとアームがピボット運動し、前記可動プレートが血液を循環系を通してポンピングするモーターと、
を更に含んでいる請求項３９の血液ポンプ装置。
【請求項４２】　アームの第２の端部が偏心軸の端部周囲と接触し、偏心軸が、ポンピング行程中にはアームを駆動し、戻り行程中にはアームの運動を拘束しない請求項４１の血液ポンプ装置。
【請求項４３】　偏心軸の端部と、アームの第２の端部との中間位置に取り付けられ且つアームと接触するロールベアリングを更に含む請求項４２の血液ポンプ装置。
【請求項４４】　モータの出力軸と、偏心軸の該出力軸と相対する端部との中間に結合した減速装置を更に含む請求項４１の血液ポンプ装置。
【請求項４５】　減速装置がプラネタリーギヤ配列構成を含んでいる請求項４４の血液ポンプ装置。
【請求項４６】　プラネタリーギヤ式の減速装置が、３ギヤ差動形式の減速装置を含んでいる請求項４５の血液ポンプ装置。
【請求項４７】　減速装置が内側リングギヤを更に含んでいる請求項４６の血液ポンプ装置。
【請求項４８】　プラネタリーギヤ式の減速装置が４つのプラネタリーギヤを含んでいる請求項４７の血液ポンプ装置。
【請求項４９】　アームが、偏心軸の回転軸線と直交する平面内に取り付けられる請求項４１の血液ポンプ装置。
【請求項５０】　アームの位置変化を検出し、血液チャンバ内の血液容量及び偏心軸の位置の少なくとも一方を決定するために駆動チャンバ内に配設された位置センサを更に含んでいる請求項３９の血液ポンプ装置。
【請求項５１】　アームの中間位置に隣り合って配設され、アームの角度変化を検出する位置センサを更に含んでいる請求項５０の血液ポンプ装置。
【請求項５２】　位置センサが渦電流センサを含んでいる請求項５１の血液ポンプ装置。
【請求項５３】　駆動機構に作動上結合され且つ駆動機構を制御するためのインプラント自在の電子制御体を更に含んでいる請求項３９の血液ポンプ装置。
【請求項５４】　血液ポンプ装置を包囲し且つ血液チャンバ少なくとも入口及び出口のためのシール自在の開口を有する包囲袋にして、組織になじむ表面を提供し且つ組織が血液ポンプ装置の可動部分間に巻込まれないようにする包囲袋を更に含んでいる請求項３９の血液ポンプ装置。
【請求項５５】　包囲袋が、該包囲袋の周囲に圧力差を生じないように変形自在である請求項５４の血液ポンプ装置。
【請求項５６】　圧縮性の血液チャンバにして、生物学的な脈管内膜ライニングの発現を促すための表面模様を施した内側表面を有する圧縮性の血液チャンバを更に含んでいる請求項３９の血液ポンプ装置。
【請求項５７】　患者の循環系に血液を供給するための方法であって、
a.　血液チャンバと、該血液チャンバの容積変化に従い移動する少なくとも１つの外側表面とを有する可変容積の血液ポンプ装置を患者にインプラントすること、
b.　前記少なくとも１つの外側表面の少なくとも一部分を、肺が該外側表面と共に移動することができるように肺の一部分に隣り合わせて位置決めし、容積可変の血液ポンプ装置のためのたわみ性が提供されるようにすること、
を含んでいる患者の循環系に血液を供給するための方法。
【請求項５８】　c.　可変容積の血液ポンプ装置に接続した位置センサからの、血液チャンバの少なくとも相対的な充満状況及び相対的な空の状況を表示する位置信号を受けること、
d.　血液チャンバの相対的な充満状況を表示する前記位置信号に応答してポンピング作動を開始すること、
を更に含んでいる請求項５７の患者の循環系に血液を供給するための方法。
【請求項５９】　血液チャンバの状況が、
a.　血液チャンバがポンピング作動を開始するために好ましい状況にあることを表示する参照信号を決定すること、
b.　位置信号の最初の導関数を計算すること、
c.　最初の導関数の符号が負であることを検出すること、
d.　そうした負の符号の検出に応答して位置信号を参照信号と比較すること、
e.　可変容積の血液ポンプ装置の速度を、位置信号と参照信号との間の差に比例して調節し、位置信号が参照信号に全体的に相当するようにすること、
により決定される請求項５８の患者の循環系に血液を供給するための方法。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は一般にインプラント可能な血液ポンプ装置に関し、詳しくは完全インプラント可能な単室型の血液ポンプ装置に関する。
【０００２】
【従来の技術】重傷の心不全症状、即ち、心臓が身体の必要とする十分な血液を送ることができなくなる症状

は、生活水準の著しい低下や莫大な医療費を、そして年間何万人もの死者を生じさせる。この病気に対処するために薬理学、生物学的な及び装置的な数多くの介入策（その多くが特許である）が考案されたが、そうした努力にも係わらず心不全は相変わらず公衆衛生上の主要な問題である。

【０００３】心不全は、心臓血液搏出量あるいは心係数が異常に小さいことで判定される。心臓血液搏出量（以下、ＣＯとも称する）は毎分当たりの血液リットル流量で測定され、心係数（以下、ＣＩとも称する）はＣＯ値を患者の体表面積（以下、ＢＳＡとも称する）で除した値として求める。通常、ＣＩ値は日中の休息時あるいは活動中は3.0～3.5である。ＣＯ値は男性では毎分5.6～6.5リットル、そして女性では体表面積が少ないこともあってそれよりもやや少ない値となる。重傷の心不全とはＣＩ値が1.5から2.0の場合である。ＣＯ値が毎分3.27であり、体表面積が1.87㎡である平均的なある男性の心不全患者の場合、ＣＩ値は1.75、毎分の心拍数（以下、ＢＰＭとも称する）は80、一回の鼓動で送り出される血液量は平均41ミリリットルである。この平均心搏血液量は、ＣＩが3.25、ＢＰＭが80の通常の男性の平均心搏血液量である76ミリリットルと対照した場合に際立って少ない。

【０００４】心臓の主ポンプ室あるいは左心室（以下、ＬＶとも称する）には入口弁（僧帽弁）と、出口弁（大動脈弁）とがある。左心室が収縮する間入口弁は閉じるので血液は出口弁を通して押し出されて大動脈に入る。左心室の拡張期圧 は2～20㎜Hg（以下、プリロードとも称する）であるが、心不全を起こしている間はこの範囲の高い方の値となる。左心室はその収縮期には、代表的には70～140㎜Hg（以下、アフターロードとも称する）であるところの大動脈圧に抗して血液を排出しなければならない。仮に心不全によってアフターロードが低下すると心搏血液量は自然に増大する。これが、ACE 抑制薬のようなアフターロード低下薬により心不全患者が助かる理由である。

【０００５】機械的な循環補助を提供する一般的方法には、反対搏動装置、例えば動脈内ポンプ（以下、ＩＡＢＳとも称する）を使用するものがある。ＩＡＢＳはアフターロード低下形式での循環補助を提供するものであり、代表的には短期的使用（即ち数時間から一日の）のために用いられる。米国特許第4,733,652号及び同第3,692,018号に夫々記載されるように、そうした装置の主たる恩恵は、心収縮期に左心室を負荷から解放させそれにより、心拡張期の冠動脈その他動脈の再潅流のための心拡張圧を増大させることによりもたらされる。この形式の処置を必要とする患者は心臓性ショック、慢性アンギナに悩まされ、あるいは手術中の循環支援（Nanas他の1988年のKormos1987）が必要となる。ＩＡＢＡ設計形状は、病院のベッドに収納する必要のある嵩張るバルン駆動ユニットを患者の体外に配置するものであり、その使用は急性用途に対してのみに限定される。

【０００６】収納した血液をポンピングするための機械的手段あるいは空気圧的手段を有するポーチ型の補助心室が米国特許第3,553,736号及び同第4,034,742号に夫々記載されている。こうした補助心室の多くは血流のための入口及び出口を共に提供する単一のアクセスポートを有している。こうした設計形状には相対的な流れの停滞が凝血形成や血栓塞栓症の危険性を増大するという不利益がある。入口及び出口の各ポートを共に有するその他の補助心室は動脈と並列結合することができる。こうした設計形状のものは、ポンピング効率を最大化することを意図した弁を有し得る（米国特許第4,195,623号及び同第4,245,622号）。

【０００７】米国特許第4,630,596号及び同第4,051,840号に記載される“動力学的動脈パッチ”は動脈に恒久的に付設するものであり、反対拍動法的な心臓補助を提供する設計形状を有している。この装置は長期使用を意図したものであることから、これを組み込むためには患者の胸部を切開する必要がある。ＩＡＢＰと同様、この装置ユニットは患者の体外に配置され、パッチは経皮的なアクセスポートを通して空気圧により膨張される。ＩＡＢＰとは異なり、この動力学的動脈パッチによれば40mlよりも大きい容量での補助を創出することができる。このシステムには恒久的な経皮的アクセスポートによる長期的な感染を受ける恐れがあること及び、インプラント外科手術時間が長くなる恐れとがある。パッチは横長の物理形状形状を有し、チャンバの血液側は柔軟なバルンから構成され、チャンバの剛性の裏張を貫いて、バルンを膨張及び収縮させるための空気圧ライン（以下、ホースとも称する）が伸延される。チャンバの剛性の裏張りの周囲は、パッチを動脈壁に縫合するためのエッジを提供するフランジとなっている。ホースは特別に設計された皮膚ポートを通して経皮的に皮膚表面に刺し通される。手術中のバルンの膨張及び収縮は、動脈内の動力学的動脈パッチに結合した外部空気ポンプを使用して行う。バルンがパルス駆動しない時、あるいはもしパルス駆動しない場合には、動脈を血流に解放させることでポンプの安全が保証される。待機モードではバルン内部を動脈圧よりも低い大気圧力としてチャンバを収縮させる。

【０００８】米国特許第4,938,766号には、動脈系にたわみ性チャンバを追加することが記載される。動脈が硬化すると管のたわみ性が低下し、心臓に加わるアフターロードが増大する恐れがある。たわみ性チャンバを加えることで、動脈硬化の影響が幾分後退し、心臓の負担が減少する。米国特許第4,938,766号によれば、そうした装置は一般に左心室を支援するために使用される。たわみ性チャンバの幾つかの形状が記載され、様々なインプラント法も教示される。この装置は、動脈に付設する単

一ポートチャンバ型、２ポートフロースルーチャンバ型、並びにバネ負荷型の各機械クリップとして分類され得るものである。フロースルー構成を持つ設計形状のものでは、たわみ性チャンバの入口側には弁が含まれ得る。この弁は逆流を防止し、より望ましい位置に向けて血液をたわみ性チャンバから優先的に排出させるためのものである。

【０００９】心拡張期における直接ポンピングは代表的には、心室補助装置（以下、ＶＡＤとも称する）と参照されるものにより実施される。フロースルー構成を有し、電気エネルギーを機械エネルギーに直接変換するＶＡＤは、本明細書で記載する従来技術として最も適切なものである。米国特許第4,091,471号には、トロイド流れ導管を内径を絞ることにより機械的に圧縮し、圧縮した導管を外径が膨張しないようにしつつ外側に押し出す装置が記載される。外径の膨張防止は、トロイド中心位置のシールされた中央部分を加圧することにより実現される。米国特許第4,250,872号には、加圧用流体により圧縮されるフロースルー構成のポンピングチャンバが記載される。この米国特許のポンピングチャンバは、主にポンピングチャンバ壁の厚さの変動に基づいてポンピングチャンバの圧縮を制御する。米国特許第5,089,016号には、液圧ポンピング流体を使用してトロイド形状のポンピングチャンバを圧縮するフロースルー構成のトロイド設計形状の装置が記載される。この装置は、ポンピングチャンバの入口及び出口の各位置に弁を有し得る。ポンピングチャンバそれ自体は全ての円周方向から圧縮されることで血液ポンピングを達成する。しかしながら、ポンピングチャンバ内の壁応力を最小化するために、壁の反対側を補強することにより、ポンピングチャンバが１方向に向けて絞られるようにするのが好ましい。

【００１０】Frazier他の出版した文献（Curculation,89:2980-2914,1994）及びMcCarthy他の出版した文献（An Thracic Surg,59:S46-S51,1995）には夫々、左上部腹壁内にインプラントされ、心搏血液量が83mlであり得るダイヤフラム駆動式の円形のポンピングチャンバを有する血液ポンプ装置が記載される。この円形のポンピングチャンバは、左心室の頂部を刺し通した導管からの血液を受ける。ダイヤフラムあるいは駆動膜は空気圧により、あるいは単一の回転ロールーカム機構を駆動する電気モータにより駆動され得る。何れの場合でもポンピングチャンバは円形であり、駆動ラインが皮膚に刺し通される。ダイヤフラムの非血液側が皮膚ポートを介して大気に通気されることから、ポンピングチャンバを適切に充填することができる。米国特許第5,569,156号に記載される血液ポンプ装置ではダイヤフラムは、ポンピングチャンバ充填中に、別の容積チャンバ（以下、ＶＤＣとも称する）に能動ポンピングされるべき作動液と接触する非血液側を有する。この血液ポンプ装置もまた、血液ポンプ装置の駆動膜と直交する入口及び出口の各ポートを有する。

【００１１】Ramasamy他の文献（ASAIO Transactions,35:402-404,1989）には、胸膜腔内に配置され、気密管手段により血液チャンバのダイヤフラムの非血液接触側と連通する、ガス充填された別個のたわみ性チャンバが例示される。このたわみ性チャンバでは、ガス充填を容易化するために、ダイヤフラムの非血液接触側を大気圧あるいは大気圧に近い圧力として血液流入を容易化させる必要がある。関連する電子部品や駆動機構を伴う人工ＶＤＡポンピングチャンバは完全にインプラントするためには今なお十分に小型化されていない。むしろ、皮膚に様々な導線を差し込み、ポンピングチャンバを外部駆動機構と接続しなくてはならない。ポンピングチャンバに血液を容易に充填することができるようにするためには、対抗する圧力を低下させる必要がある。前述の各文献にはこの圧力低下を実現するための３つの手段、即ち、皮膚を通しての大気圧力への通気、胸腔内の、ガスを充填した別個のたわみ性チャンバへの通気、そして、インプラントした容積チャンバあるいはＶＤＣに結合した中間作動液を使用することが記載される。Frazuer他の文献に記載されるポンピングチャンバは、このポンピングチャンバが左心室頂部からの血液を受け、受けた血液を左心室と平行な流路を越えて大動脈に送り込むようにされ、かくして左心室と平行な血液流路を有している。

【００１２】

【発明が解決しようとする課題】従って、解決しようとする課題は、関連する電子部品と共に完全にインプラントされ、経皮的な導線に関連する感染の恐れを回避することのできる、十分に小型の血液ポンプ装置に対する需要を満たすことである。解決しようとする他の課題は、ポンプの一部或は気密管を使用してポンプに接続した別個のチャンバの何れのチャンバ形態のものであれ、たわみ性のための第２のチャンバを必要とすべきではない血液ポンプ装置を提供することである。解決しようとする更に他の課題は、平行な結合通路とは対照的に、大動脈基部から低い充填圧力下に血液を受け、受けた血液を、ポンプを駆動して、遠方の大動脈に於けるそれよりもずっと高圧のものとして血液を上行大動脈に戻す血液ポンプ装置を提供することである。そうした接続構成は、左心室と“直列”であると参照され得る。

【００１３】

【課題を解決するための手段】本発明に従うインプラント可能な血液ポンプ装置は、ポンプ部分と、駆動機構を収納する駆動チャンバとを有するポンプハウジングを含み得る。ポンプ部分は平坦あるいは、ポンプハウジングに結合することのできるコップ状のプレート部材であり得る。駆動機構は、ステータと、ロータと、出力軸とを有する電気サーボモータを含み得る。出力軸は、カム部分を有し得る偏心軸に結合することができる。カム部分

はロールカムであって良く、カムに追従する一端部を有するポンピングアームを提供し得、ポンピングアームの中間部分はハウジングにピボット廻動自在に装着することができる。ピボット廻動自在に取り付けたポンピングアームの端部はカム表面と間欠的に接触し、ポンピングアームの端部の表面がカム従動節として作用する。ポンピングアームの他端は可動プレートに結合することができる。入口及び出口を循環系に結合した圧縮性の血液チャンバを、コップ形状部分と可動プレートとの間に挟持させることができる。血液チャンバの出口位置には、動脈血が確実に一方向のみにおいて血液チャンバを通過するのを助成するための弁を設けることができる。かくして、電気サーボモータはカムを回転させ、カムが回転するとポンピングアームが回転中心、即ち、固定した中間部分を中心としてピボット廻動する。ポンピングアームのピボット運動により可動プレートが血液チャンバを周期的に圧縮及び釈放し、循環系を通して血液をポンピングする。血液ポンプ装置の可動プレート側を肺に隣り合う位置にインプラントし、可動プレートが移動して血液がポンピングされるに際して肺がこの可動プレートと共に移動するのが好ましい。従って、肺を血液ポンプ装置のためのたわみ性チャンバとして利用することができる。結局、たわみ性チャンバを別に設ける必要性がなくなる。電気サーボモータと偏心軸との間に減速装置を結合するのが好ましい。減速装置は、４つのプラネタリーギヤを持つギヤ配列構成を有し得る。更には、密封シール用の金属製のベローズ部材を駆動チャンバ及びポンピングアームの中間部分の周囲に設けることができる。ベローズ部材は、ポンピングアームの端部の周囲において駆動チャンバをシールしそれにより、駆動機構が体液と接触するのを防止する。ベローズ部材は空間を密封シールすると共に、駆動アセンブリの運動をそうした密封シールを破ることなく伝達するための手段を提供する。

【００１４】血液ポンプ装置の一部分のみあるいは全てを、好ましくは等張塩水溶液を充填した高分子製の包囲袋で囲み、組織を取り巻く親組織表面を提供させることができる。包囲袋は、組織が血液ポンプ装置の可動部分に巻込まれるのをも防止する。血液チャンバ内の相対血液容量を決定するための位置センサを位置付けることができる。血液チャンバ内の相対血液容量は、血液チャンバ内の血液量及びカム位置を共に表示する情報となり得る。この情報は、特に、血液チャンバからの血液排出を開始すべきであるときにモータ速度を制御してポンプ作動を最適化するために使用することができる。血液ポンプ装置は様々な構成においてインプラントされ得る。標準の人工血管を入口及び出口のために使用することができる。出口カニューレを胸部上行大動脈に接合し、入口カニューレを、胸部上行大動脈に（直列に）接合して出口カニューレに弁を１つだけ設けるかあるいは、左心室（ＬＶ）の頂部に（平行に）接合し、入口及び出口の各カニューレに一体型の弁を設けることができる。

【００１５】血液ポンプ装置の運転を制御するための幾つかの機能を提供させるための、密封シールした電子制御体をインプラントすることもできる。心臓にＥＣＧ導線を結合し、電子制御体に信号を供給させることができる。そうした信号はペーシングを制御するために、また更には即時徐細動のために使用することができる。同じＥＣＧ導線を使用して、必要であれば患者の心臓をペーシングすることもできる。心不全患者の多くは心室細動（突然心臓死）を起こす危険性が高いことから、電子制御体から電気徐細動/徐細動導線を引き出すこともできる。この電子制御体への電気エネルギーは、経皮エネルギー及びデータ伝達システム（以下、ＴＥＤＴＳとも称する）を介して供給することができる。ＴＥＤＴＳはカプセル封入した、皮下（二次）コイルを利用することができる。皮下コイルは結局、電子制御体に接続される。皮下コイルと合致する外部（一次）コイルを患者の皮膚に固定し、エネルギーを電子磁気的に二次コイルに伝達し、電子制御体を作動させることができる。こうしたコイル組合せ体を、電子制御体と、外部の検出及びプログラム装置との間でデータを双方向的に送るために使用することも可能である。電力及びデータを経皮的に送るための１つのそうしたシステムは米国特許第5,630,836号に記載される。電子制御体のバッテリーは通常のＴＥＤＴＳ作動中にチャージされ得る。もしＴＥＤＴＳの外部コイルを患者の皮膚から取り去る、あるいはそうでなければもしＴＥＤＴＳの電力が低下した場合には、電子制御体のバッテリーパックがインプラントシステムを数時間作動させるために必要な電力を提供することができる。

【００１６】

【発明の実施の形態】図面を参照して本発明を説明するに、図１から図７には完全インプラントが可能な血液ポンプ装置１０が例示され、患者の循環系に関連する構成部品、例えば電子制御体（以下、ＥＣとも称する）２００、バッテリーパック２１０、ＴＥＤＴＳ２２０と共に運転上結合されている。血液ポンプ装置１０は左右何れかの胸部にインプラントすることが可能であり、並列構成かあるいは直列構成下に循環系に接続することができる。図１及び図５には別態様の、並列構成で心室を補助するための右胸部インプラント構成が例示される。図４には並列構成で心室を補助するための左胸部インプラント構成が例示される。左右何れかの胸部インプラントにおいても、血液ポンプ装置１０は人体（あるいは人体以外の動物）の胸部内に、血液が左心室頂部から上行大動脈へと流路を取る状態下にインプラントすることができる。血液ポンプ装置１０は、肺がこの血液ポンプ装置の動作側を若干押すように位置決めすることができる。このように配置することにより、血液ポンプ装置１０は肺組織を用いた自動たわみ性のものとなり、別個のたわみ

性チャンバに対する必要性が排除される。ポンピング機能もまた、血液流れ導管と一層直接的に係わるものである。

【００１７】任意の構成の血液ポンプ装置１０を、図２及び図３に示すように、心臓とほぼ同じ高さの位置で胸壁の内側に配置することができる。血液ポンプ装置１０が血液チャンバ２０を圧迫すると血液チャンバ２０は排出された血液容量分薄くなることが示される。かくして、肺が血液ポンプ装置１０のためのたわみ性チャンバとして作用することとなる。これは、たわみ性を得るためにガス充填した人工チャンバを必要とする従来からの血液ポンプ装置アセンブリに勝る明らかな利益をもたらす。人工チャンバは時間が経つと放出によってガス容量が失われ、結局、定期的に再充填してその能力を維持させる必要がある。大抵の従来システムでは血液ポンプ装置アセンブリは胸部に組み入れるには大き過ぎる。そうした従来システムではたわみ性チャンバは血液ポンプ装置アセンブリとは全く別の構成部品であり、空間があれば別の場所にでもインプラントされ得るものである。そのため、たわみ性チャンバを血液ポンプ装置アセンブリに接続するための気密性の管状接続部が設けられる。自動たわみ性の血液ポンプ装置ではインプラントされる構成部品は少なくなり、インプラントのために必要な空間もずっと少なくて済む。従って、本発明は別個にたわみ性チャンバを必要とする従来からの血液ポンプ装置アセンブリよりも実質的にずっと空間効率的である。

【００１８】胸郭内の肺空間を使用してたわみ性を得るようにすることで数多くの利益を得ることができる。例えば、肺空間内の圧力は大気圧に極めて近いことからポンピングチャンバを充填するための理想的な状況が提供され、その一方で、たわみ性チャンバに対する必要性が排除される。更に、人体にとって、インプラントする必要のある部品が少ない方が良いことは言うまでもない。肺は極めてたわみ性に富んでおり、全体的に、若干の圧縮及び膨張に対しても肺機能に悪影響を受けるあるいは損なうことなく耐え得るものである。人工的なたわみ性チャンバとは異なり、肺は“漏れ”を生じたりはせず、従って定期的に再充填する必要もない。しかも、胸郭が血液ポンプ装置を保護する。血液ポンプ装置は胸壁の内側で、心臓に隣り合って肋骨に接触する状態で図４に示すように配置され得る。ポンピングチャンバが全体的に扁平であることにより、肺機能との干渉は最小程度であり、占有空間は効率的に使用される。

【００１９】血液ポンプ装置１０には、図７及び図８に示されるように、直列構成下に循環系に取り付けることもできる。従来からの心室補助装置、即ちＶＡＤは代表的には、図１、図５、図６に示すような並列構成下に循環系に取り付けられ、その場合は、入口導管が左心室頂部２からの血液を受ける。そうした配列構成では血液は心室底部から血液ポンプ装置に流入する。従来のＶＤＡでの血液流路は通常の左心室の血液流路と平行とされ、従って、ＶＡＤの血液ポンプ装置が故障するとこれらの平行な血液流路は血栓によって詰まる恐れがある。直列構成の場合、血液ポンプ装置が故障すると血液流路は通常よりも長くなるが、血液は血液ポンプ装置へと送られ続けるので血栓は起こりにくくなる。従って、直列構成は、血液ポンプ装置が故障した場合でも並列構成と比較してより安全である。左心室からの血液が、並列構成においてそうであるように左心室の頂部から送り出されるのに代えて、通常的に大動脈弁を通して送り出されることから、血液ポンプ装置故障時に血液ポンプ装置内で血流が詰まる恐れが少なくなるのみならず、左心室内で血流が詰まる高い危険性も減少する。直列構成とする場合の他の長所は、血液ポンプ装置の出口導管内にただ１つの弁を設ければよいことである。対照的に、並列構成では入口及び出口の各導管に対して各１つ、合計２つの弁を設ける必要がある。こうした弁は長い導管の内部に設けるかあるいは連結器アセンブリの一部とされる。何れの場合でも機械的あるいは生物置換性の弁が使用される。しかしながら、直列構成の血液ポンプ装置では心臓の本来の大動脈弁が血液ポンプ装置の入口弁として作用し得るので、出口導管にただ１つの弁を位置付けるだけで良い。

【００２０】循環系に導管を取り付けるための従来の技法が図９から図１２に例示される。導管は、スプール形式の連結体を使用して、あるいは予め製造したクイックコネクタを使用して縫合することにより血液ポンプ装置に接続することができる。スプール形式の連結体は、この連結体を覆い、バンドあるいは結紮により連結体に締着した人工血管を有する設計形状を有する。クイックコネクタは、導管を血液ポンプ装置に結合するための合致する端部を有する。血液ポンプ装置１０の端部及びポリウレタン製のサックの端部は、使用する連結部の形式に係わらずこれらの連結部の位置で終端される。

【００２１】図９から図１１には直列構成でのインプラント技法が例示され、胸部上行大動脈が流入導管への接続のために露呈されている。サティンスキ（satinski）クランプを使用して動脈壁の１セグメントをピンチ止めする一方で、通常の動脈流れは妨害することなく維持される。流入導管を組み込む準備に際し、動脈のクランプ止めしたセクションを長く切開する。次いで、外科的縫合を使用して動脈の側部に流入導管の端部を縫合する。近接する側のクランプを取り外し、皮下注射針を使用して流入導管から空気を抜く。空気抜きした後、遠方側のクランプを取り外す。これにより上行動脈内に、左心室からの血液を血液ポンプ装置を通して直列的に動脈系に送れるようにするための動脈分離部あるいは絞窄部が創出される。直列構成の導管を動脈に接続するために、心臓バイパスとの端部間接合を使用することもできる。

【００２２】図１２から図１４には並列構成でのインプ

ラント技法が示され、胸部上行大動脈の１セグメントがカニューレ組み込みのために露呈されている。単一のサティンスキ（satinski）クランプを使用して動脈壁の１セグメントをピンチ止めし、その一方で、通常の動脈流れは妨害することなく維持させる。カニューレを組み込む準備に際し、動脈のクランプ止めしたセクションを長く切開し、次いで、外科的縫合を使用して動脈の側部にカニューレの端部を縫合する。縫合したカニューレは血液ポンプ装置の出口導管として使用される。次いで、左心室頂部にカニューレを組み込み、このカニューレを血液ポンプ装置の入口導管に接続する。この並列構成で結合された血液ポンプ装置は、左心室頂部に開口を有することによる空気閉栓症の恐れがあることから、インプラントのための心臓バイパスがおそらく必要である。

【００２３】図１５及び図１６には従来からのクイックコネクタアセンブリ８０が示される。血液チャンバ２０の入口２４あるいは出口２２はアクチュエータ隔壁８４に結合されている。錠止用スリーブ８８をアクチュエータ隔壁８４に取り付け、クイックコネクタアセンブリ８０のクイック連結部のための固定先端とすることができる。人工血管１１０を支持体リング８６に接合することができる。支持体カラー９２が支持体リング８６を取り巻き、一体の２つの錠止用ピン９０を有し得る。支持体リング８６と支持体カラー９２との間には圧縮バネ９４を設け得る。圧縮バネ９４は支持体リング８６と支持体カラー９２との間で圧縮され、錠止用ピン９０により然るべき位置に保持される。錠止用ピン９０は支持体リング８６内の長孔９８内を摺動自在である。支持体リング８６と支持体カラー９２との間にはＯ－リング８２を配置することもできる。Ｏ－リング８２は支持体カラー９２により然るべき位置に保持される。支持体カラー９２と錠止用スリーブ８８との間には別のＯ－リング８２を配置することができる。このようにして、クイックコネクタアセンブリ８０は体液に対してシールされ得る。クイックコネクタアセンブリ８０のアクチュエータ側端部にはアクチュエータ隔壁８４と、入口導管２４あるいは出口導管２２と、Ｏ－リング８２と、錠止用スリーブ８８とが含まれる。クイックコネクタアセンブリ８０の導管側端部には血液流れ導管、即ち人工血管１１０と、錠止用ピン９０と、支持体カラー９２と、圧縮バネ９４と、Ｏ－リング８２とが含まれる。組立に際し、導管側端部とアクチュエータ側端部とを寄せ合わせ、錠止用ピン９０を錠止用スリーブ８８の長孔１００に通す。次いで各端部を前進させ、支持体カラー９２を時計方向に回転させて錠止用ピン９０を錠止用スリーブ８８の長孔１００の通路に沿って移動させる。連結が完了すると、Ｏ－リング８２によりクイックコネクタアセンブリはその内側が人体からシールされ、錠止用ピン９０と圧縮バネ９４とにより然るべく保持される。別態様でのクイックコネクタアセンブリを使用することができることを理解されたい。クイックコネクタアセンブリを用いることで、ポンプが存在することによる物理的干渉を受けずに、デリケートな円形の連結部を外科的に縫合し得ることが重要である。外科医は、導管を循環系に連結する縫合に引き続き、クイックコネクタアセンブリを使用して素早くポンプを装着することができる。

【００２４】血液チャンバ２０は弾力圧縮性と生物安定性とを有する医薬等級のポリウレタン、例えば、米国特許第5,133,742号に記載されるような形式のポリウレタンから作製することができる。血液チャンバ２０の、血液と接触する内側表面は、生物学的な血液接触表面を形成するための内側に延びる組織表面を提供するよう、一体的な表面模様が施され得る。表面模様は、血液チャンバ２０の表面に直交して配向された短繊維から成り立ち得る。そうした表面模様は米国特許第751,839号に記載されるものであり得る。繊維による表面模様付けは、生物学的な内膜ライニングの発現を促進し得るものである。内膜ライニングは血液チャンバ２０及び人工血管１１０全体を縫い目無しに伸延するのが好ましい。なぜなら、ダクロン（商標名）製の人工血管もまた、内側に延びる組織を好ましく発現させそれにより、人工血管内部に生物学的な表面を生じ得るからである。血液チャンバ２０は全体的にフロースルー型の設計形状を有し、渦流あるいは流れ停滞帯域が最小化されるように断面積の変化は最小であり得る。

【００２５】血液チャンバ２０はそれ自身、実質的には菱形形状を有し、胸郭の何れの側に血液ポンプ装置１０を位置決めするかによって、また、直列あるいは並列の各循環連結形式の何れかを選択するかによって様々な構成で形成され得る。例えば、図１７から図１９には幾つかの異なる構成が例示される。図１７には血液チャンバは胸部右側に並列形式で連結するための構成が例示される。胸部左側に並列的に連結する鋼製ものでは血液チャンバは図１７に示されるものと鏡像をなすものとなる。胸部右側に直列接続するためには血液チャンバ２０は、図１９に示すような、入口及び出口を相互に実質的に反対側に位置付ける構成のものとなり得る。しかしながら、胸部右側に直列接続した別態様では血液チャンバ２０は、図１８に例示するような非フロースルー型の“ブラインドポーチ”構成に形成され得る。血液チャンバ２０の材料組成は特定の構成に係わらず同じであり得る。何れの構成であれ、血液チャンバ２０は先に参照した医薬等級のポリウレタンから作製され得る。

【００２６】図２０から図２６を参照するに本発明に従う血液ポンプ装置が示され、ポンプハウジング１３がコップ状部分１５と、駆動チャンバ１８と、血液チャンバ２０と、駆動機構とを有している。駆動機構にはポンピングアーム３３と、可動プレート２８とが含まれる。ポンプハウジング１３と、ポンピングアーム３３と、可動プレート２８とは全てチタンから構成するのが好まし

い。血液チャンバはポンプハウジング１３のコップ状部分１５内に位置決めすることができる。コップ状部分１５は、血液チャンバ２０の入口２２及び出口２４のための開口１６を有し得る。コップ状部分１５は図ではコップ状に示されるが、全体的に平坦な底板を用いることもできる。可動プレート２８は、この可動プレート２８が押し付けられるところの血液チャンバ２０の表面よりも好ましくは若干小さい表面積を持つことを除き、血液チャンバ２０と全体的に相当する形状を有し得る。血液ポンプ装置１０を患者にインプラントするに際しては、血液ポンプ装置１０の可動プレートの少なくとも一部分が、患者の肺５の少なくとも一部分に隣り合って位置付けられるように位置決めするのが好ましい。そうすることにより肺５は、可動プレート２８が血液をポンピングするために図２から図３に例示するように移動するに際して、可動プレート２８と共に移動することができるようになる。結局、血液ポンプ装置１０の容積の変化分は、肺がこの血液ポンプ装置１０のためのたわみ性チャンバとして作用することで補償される。

【００２７】図２１並びに図２３乃至図２４に示されるように、可動プレート２８の縁部は、血液チャンバ２０が圧縮される時に可動プレート２８の縁部位置に応力が集中しないようにするために、血液チャンバ２０から離れる曲線形状を有するのが好ましい。血液チャンバ２０並びに可動プレート２８の寸法形状は、血液チャンバ２０が加圧されて圧縮されるに際し、血液チャンバ２０の柔軟な部分に生じる曲げ応力及びフープ応力が最低になるように最適化することができる。血液チャンバ２０は繰り返して変形可能であり、しかも尚、その実質的な変形前の状態に復帰することが可能であるべきである。曲げ応力は、血液チャンバ２０が全圧縮に耐え得る適宜の壁厚を注意深く選択することにより対処することができる。血液チャンバ２０の入口２２及び出口２４は血液チャンバ２０の最大の突出部分の平面内に位置付けるのが好ましい。結局、血液チャンバ２０は最も薄い輪郭のものとなり得る。

【００２８】理論的には、血液チャンバ２０を最適化するためには数多くの複雑な現象を考慮する必要性が生じ得る。先ず第１には、血液チャンバ２０の受ける偏倚量は図２３及び図２４に示すように大きいが、材料の単純強度の原理ではこの現象を説明することはできないことである。なぜなら、大きな変形やたわみを表すところの材料の挙動の成分は単純化のために省略されるからである。所定の血液チャンバ２０の特定の三次元形状が説明されるべきであるのに対し、“教科書的”な解答は簡単な形状及び成分に対してのものであると言う点も複雑化を招く原因である。第２には、本発明で使用する高分子は応力と応力変形との関係が非線形であるという特性を有することであり、第３には、血液チャンバ２０が可動プレート２８の縁部の周囲に折れ曲がるに際しての局部的変形はそれ自体が複雑な接触現象であり、可動プレート２８の形状や血液チャンバ２０の厚さに直接関わるものであると言う点である。こうした要因を考慮しつつ血液チャンバ２０を評価する実用的な１方法は有限要素分析法を使用するものである。この解決策では、問題となる成分がずっと小さく且つ単純な部分（要素）に分解される。次いで、各要素は同時に解決され、要素を公式化するに際して複雑性が説明される。上述した問題に対しては、かなりのコンピュータ資源及び計算時間が必要となる。

【００２９】本発明の血液チャンバ２０は血液ポンプ装置１０の運転中に曲げ及び圧力に起因する応力変形とを同時に受ける。先に述べたように、そうした曲げは可動プレート２８の縁部の形状及び血液チャンバ２０の厚さに係わるものである。血液ポンピングによって生じる応力変形もまた、血液チャンバ２０の厚さのみならず、圧力負荷を受ける状態にある部分の長さS_Fによって決まる。要するに、この長さS_Fが長くなる程、血液チャンバ２０に加わる圧力負荷は大きくなる。血液チャンバ２０を厚くすると圧力に起因する応力変形量は減少するが、血液チャンバ２０が可動プレート２８の周囲に曲がる際の応力変形量が増大する。かくして、設計上の問題には、曲げ及び圧力による各応力変形をバランスさせることが含まれる。次いで、可動プレート２８の縁部形状と、血液チャンバ２０の部分長さS_Fと、長さS_Fでのチャンバ幅とを変化させることにより最良の性能をもたらす血液チャンバ２０形状を決定する必要がある。

【００３０】高分子製の構成部品は代表的には、この構成部品の寿命に対する所定の応力変形水準を維持するような設計形状を有している。従って、所定の材料及び負荷頻度に対して許容される最大の応力変形量を知ることが必要となり得る。従来の研究によれば、本発明のために使用するポリウレタンに対しては２００万サイクルに対して最大15%の応力変形が許容され得ることが示された。結局、この応力変形水準を、本発明のポリウレタン製の構成部品の設計上の許容最大応力変形量として使用することができる。

【００３１】図２５及び図２６を参照するに、駆動機構は、偏心軸４７を回転させるための、減速装置７０に連結した電気式のサーボモータ５６を好ましく含み得る。偏心軸４７はポンピングアーム３３と可動プレート２８とを駆動して血液をポンピングすることができる。サーボモータ５６にはステータ部分５８とロータ部分６０とが含まれる。ステータ部分５８はハウジングに剛着され、ロータ部分６０は偏心軸４７を回転させてポンピング作動を発生させるための出力シャフト６２を含み得る。サーボモータ５６を電源及び或はＥＣ２００に接続するための電力カップリング７９を設けることができる。サーボモータ５６は種々の寸法あるいはアスペクト比を有し得る。サーボモータ５６はおよそ2,000～3,000

RPMで連続回転し得るものが好ましい。サーボモータ５６は、例えば、カリフォルニア州CarlsbadのSierracin/Magnedyne社の製造するものであり得る。サーボモータ５６は毎分120拍の速度で血液をポンピングし、血液ポンプ装置の行程容積は60～80mlであるのが好ましい。加えて、血液ポンプ装置は行程容積での血液を人間の動脈圧力の範囲での圧力に抗して血液を移動させ得るべきである。心不全患者の場合、そうした動脈圧力範囲は、一般にその最大値において約160mmHgである。こうした基準を使用して、血液ポンプ装置１０血液チャンバ２０、ポンピングアーム３３、サーボモータ５６、減速装置７０その他の構成部品の設計を最適化することができる。更には、サーボモータ５６及び減速装置７０は静音運転、受容し得る発熱量、そして、好ましくは少なくとも５年の、メンテナンスフリー状況での長い作動寿命のためにも設計されるべきである。

【００３２】減速装置７０は出力軸６２と偏心軸４７との間に結合するのが好ましい。減速装置７０は、サーボモータ５６の回転運動を毎分約80及び120の間のサイクル数に変換する、ギヤ比が25:1の、図２６に最も良く示されるようなプラネタリーギヤ式の減速装置であるのが好ましい。サーボモータ５６の速度及び減速装置７０の比は、エネルギー効率を達成し且つ最もコンパクトな駆動機構を提供するように選択することができる。減速装置７０の出力軸の１回転が血液ポンプ装置１０を１工程作動させ、この行程作動が毎分約60～120サイクルの範囲で生じる。市販入手することのできるプラネタリーギヤ式減速装置には様々なものがあるが、寸法形状の最小化と効率の最大化とを両立させるためには注文設計のものを使用するのが好ましい。プラネタリーギヤ式減速装置７０は、図２６に示すような３ギヤ差動（以下、ＴＧＤとも称する）型のものであり得る。その他の形式のギヤ式減速装置を使用することができるが、ＴＧＤは中でも小型で且つエネルギー効率的であることから好ましいものである。この形式の減速装置７０には内側リングギヤが含まれ得る。内側リングギヤは係合時の滑りが少なく、負荷をより漸次的に伝達するための接触比が高いことが知られている。更に、ＴＧＤは、所定寸法に対する負荷担持容量が大きいのみならず寿命も長く、その他の形式の減速装置よりも高効率且つ低騒音である。ＴＧＤは、より一般的な４ギヤ差動型のものよりもギヤが１つ少なく、従って小型化することができる。プラネタリーギヤは４個を使用するのが好ましい。そうすることで負荷通路は４倍となり、全体の形状をプラネタリーギヤ数がもっと少ないものよりもずっと小型化することが可能となる。

【００３３】減速装置７０の出力軸を偏心軸４７に結合することができる。図２５に最も良く示されるように、偏心軸４７は減速装置７０により駆動され得るリングギヤ部分６８を取り付けた入力部分４８を有し得る。ポンピングアーム３３は偏心軸４７の端部周囲に乗る形で接触する。結局、偏心軸４７はポンピング工程中にポンピングアーム３３を駆動するが、ポンピングアーム３３は血液チャンバ２０が充填される間の戻り工程中は拘束されることなく自由運動する。ロールベアリング５２であり得るカムが偏心軸４７の端部に取り付けられ、ポンピングアーム３３の端部はこのカムに従動する。偏心軸４７の回転中心は$C_{軸}$として示される。

【００３４】ポンピングアーム３３は、サーボモータ及び減速装置の回転軸と直交する平面内に配向するのが好ましい。ポンピングアーム３３の中間部分にピボット廻動自在に取り付けた部分の回転中心$C_{アーム}$の位置にベアリング４３を設け得る。非腐食性で低摩耗性の、図示しない高分子製スリーブを、可動プレート２８にポンピングアーム３３を結合するためのベアリングとして使用するのが好ましい。この連結部のために好ましい材料はＰＰＳスリーブ材料及び３１６ステンレス鋼である。ポンピングアーム３３の、カム表面と接触する側の端部はカム従動節４５として作動する。カム５２が偏心軸上で回転するに従い、ポンピングアーム３３はその回転中心$C_{アーム}$を中心として、図２２に最も良く示されるように周期的に揺動し、血液チャンバ２０の周期的ポンピングが達成される。ピボット運動するポンピングアーム３３の回転中心から各端部までの距離の比は図２１ではD_1及びD_2として表され、ポンピングアーム３３の所定の幾何形状において可能であるてこ比を決定する。ポンピングアーム３３の回転中心から可動プレート２８までの距離D_1はカム５２の表面までの距離よりも大きいのが好ましい。偏心軸４７のためのトルク条件は、ピボットアームのてこ比によりもかなり大きなものとなり得る。しかしながらそれにより、エネルギー変換用ハードウェア（サーボモータ、減速装置、カム）を偏心軸４７の回転中心$C_{軸}$に近づけて位置決めすることができるようになりそれが、駆動機構の一層の小型化を可能とする。ポンピングアーム３３の中間部分に隣り合う位置に位置センサ３９を設けるのが好ましい。位置センサ３９は、例えば、ポンピングアーム３３の位置変化を検出するための渦電流センサであり得る。ポンピングアーム３３の位置変化から血液チャンバ２０内の血液の相対容量を決定し、また、偏心軸４７やカム５２の位置を決定することができる。

【００３５】可動プレート２８は、ポンピングアーム３３の端部４１の取り付け部分となり得る中央結合ポイント２９を有し得る。可動プレート内の穿孔及びポンピングアーム３３の端部４１の穿孔を貫いてピン３０を配置することができる。これにより、ピン３０がポンピングアーム３３を可動プレート２８に蝶着する。ポンピングアーム３３は可動プレート２８と直交する平面内を揺動するのが好ましい。ポンピングアーム３３を蝶着したことにより、可動プレート２８はそれ自身、工程動作中に

血液チャンバ２０の応力変形が最小化され得るような方向に配向され得る。ポンピングアーム３３の回転中心$C_{アーム}$は駆動チャンバ内に設けるのが好ましい。

【００３６】カム５２の表面がポンピングアーム３３と間欠的に接触することから、駆動機構はカム回転の圧縮相の間のみ作動し、その場合でも血液チャンバ２０に血液が充満されるまでだけ作動する。かくして、血液ポンプ装置１０はカム表面の後退相の間は血液チャンバ２０に充填された血液のみをポンピングする。このように、可動プレート２８は血液チャンバ２０が充満されている間はサーボモータと切り離され、しかも尚、血液チャンバ２０をポンピングすることなく連続的に上下動する。これにより、完全に充満されていない血液チャンバ２０をポンピングした場合、血液チャンバ２０の膜に望ましからざる皺が発生し及び或は左心室の圧力が過剰に低下するのが防止される。

【００３７】ポンピングアーム３３及び駆動チャンバ１８の回転中心$C_{アーム}$を覆い且つ密封シールし、体液を駆動機構から遠ざけておくためのシールベローズ３８を好ましく設けることができる。シールベローズ３８の何れかの端部には端部キャップ３６、３７を設けることができる。前方側の端部キャップ３７はポンピングアーム３３の周囲にシールされた開口を有し、この開口を通してベローズ部分３５が駆動チャンバ１８に通じている。シールベローズ３８はチタンから作製するのが好ましい。シールベローズ３８はそれにより、エネルギー変換用の構成部品が非生物相容性の潤滑流体を有することが可能となり、また、腐食性の硬質の鋼が人体の塩水（saline）環境からシールドされることから重要な特徴部分である。シールベローズ３８を設けることにより、ギヤ、ベアリング、モータが腐食する恐れが大きく減少され得る。そうした部品の腐食は体液が駆動チャンバ１８中に拡散することによって発生し得るものである。シールベローズ３８は駆動チャンバ１８を密封しつつも尚、サーボモータ５６の機械的エネルギーを可動プレート２８に伝達可能ならしめる。更には、モータ駆動アセンブリが密封シールされることで、保護潤滑環境下で約５年あるいはそれ以上作動する硬化鋼製のベアリング、ギヤその他部品を使用することができるようになる。硬化鋼製の部品を使用するのは、硬化鋼製のベアリングやギヤその他のモータ駆動部品の回転摩擦により、電気モータに入力する電力エネルギーを高効率で血液作業に伝達することができることから望ましい。エネルギー変換用ハードウェア（サーボモータ、減速装置、カム）を回転中心$C_{軸}$に接近して位置決めすることにより、駆動機構全体をより小型化することが可能となりそれが、シールベローズにより誘起される運動を最小化する。結局、駆動機構をより実用的に密封シールすることができるようになる。

【００３８】高分子製の包囲袋１０５を図２及び３に示されるように血液ポンプ装置１０の周囲に設けることにより、血液ポンプ装置１０を取り巻く患者の組織になじむ表面を提供するのが好ましい。この包囲袋１０５を少なくともポンピングアーム３３及び可動プレート２８で包囲し、ポンピングアーム３３の作動領域内で組織が巻込まれないようにするのが好ましい。包囲袋１０５は弾性変形自在であり、包囲袋１０５の上部並びに周囲に差圧が生じないような状態下にに可動プレート２８と共に移動する。更には、包囲袋１０５はこの包囲袋１０５の領域内に向けての組織の成長を防止ししそれが、そうした組織へのポンピングアーム３３の引っ掛かりを未然に防止する。血液ポンプ装置１０全体を、必要であれば包囲袋１０５内部に収納することもできる。

【００３９】並列あるいは直列の何れの血液流れ構成であっても、血液ポンプ装置１０は心臓１と同期してあるいは同期させずに運転することができる。同期運転では代表的には血液ポンプ装置１０は、左心室が収縮する毎に血液を排出する。血液ポンプ装置１０の血液排出のタイミングは、左心室が血液を排出（収縮）する時の心臓の電気的活性度（ＱＲＳ）を検出することにより制御される。この電気的活性度が検出されたとき、血液ポンプ装置１０は血液を即座にあるいはプリセットされた遅延時間の後に排出することができる。しかしながら血液ポンプ装置１０の血液排出は、左心室が血液排出を終えた後に行われるのが好ましい。非同期的運転ではしばしば血液ポンプ装置１０はＱＲＳとは無関係に血液を排出する。同調モードでは血液ポンプ装置１０は例えば、ＱＲＳ信号検出後のプログラムされた遅延時間の後かあるいはインプラントした電子的制御体からの刺激性のペーシングパルスの後に収縮される。非同期モードではポンピングは、位置センサ３９が血液チャンバがほぼ充満状態となったことを検出したとき、例えば電子的制御体２００によって開始され得る。

【００４０】非同期モードではサーボモータ５６を比較的一定の速度で運転し、回転質量の加減速に関連する反力及び動力損失を最小化するのが望ましい。サーボモータ５６の速度は、血液チャンバ２０が各血液排出相を開始する時点でほぼ充満されるように調節するのが理想的である。回転速度があまりに遅いと血液チャンバ２０は血液排出相の開始以前に膨張して血液の流入を制限する。これは左心室の圧力を過剰に高める恐れがある。逆に、回転速度が速すぎると血液チャンバ２０から排出される血液量は各サイクル中に血液チャンバ２０の内側表面を適切に洗い流すためには少な過ぎるものとなる。更に、回転速度が速過ぎた場合には摩擦や粘性による動力損失量が不必要に大きくなる。

【００４１】図２７には、血液チャンバ２０が各排出相の開始時点でほぼ充満するようにモータ速度を最適制御するための１手段が例示される。曲線１００は減速装置の出力軸のカムのサイクル運動を表す。線１０２で示さ

れる位置ではカム５２は完全に引き込まれ、ポンピングアーム３３は血液チャンバ２０がその最大充満位置に充填される際の自由浮動状態にある。線１０３の位置ではカム５２は１８０°回転され、ポンピングアーム３３を介して血液チャンバ２０を最大限に圧縮する。血液チャンバ２０は、線１０４で示される血液流入相の間に左心室から送られる血液で自由に充満される。線１０５で示される血液排出相では血液チャンバ２０はカム及びポンピングアーム３３の作動により圧縮され、血液チャンバ２０からの血液が排出弁を介して動脈に送り出される。線１０６、１０７、１０８は、ポンピングアーム３３の位置を検出する位置センサ３９からの推定出力値、つまり血液チャンバ２０内の血液の相対容量を示す。線１０６は、モータの回転速度があまりに遅い場合の、血液チャンバ２０が血液排出相１０５が開始される以前に完全に充填され、カム５２が位置１０９の時にのみポンピングアーム３３の運動を拘束するようになる状況を表す。線１０８は、モータの回転速度が速すぎる場合、即ち、血液チャンバ２０が血液排出相１０５の開始時点では部分的にのみ充満され、カム５２は位置１１１の時にのみポンピングアーム３３の運動を拘束するようになる状況を示す。線１０７は、モータ回転速度が適正に調節され、血液チャンバ２０が血液排出相１０５の開始時点でほぼ完全に充満され、カム５２が血液排出相１０５の開始直後の位置１１０で、ポンピングアーム３３の運動を拘束するようになる状況を例示する。図２７の番号１０９、１１０、１１１でそれぞれ表されるカム/ポンピングアームの接触位置は、位置センサ３９の出力の最初の導関数が負になることで容易に検出することができる。モータの回転速度はカムとポンピングアームとの接触位置の検出値を理想の接触位置１１０と比較し、検出される接触が早すぎる場合にはモータの回転を上げ、接触が遅すぎる場合にはモータ回転速度を減速することにより最適に調節することができる。

【００４２】同期モードでは血液チャンバ２０はＱＲＳ信号と同期され、左心室の収縮相の間血液を受け、次いで左心室の膨張相の間に血液を排出する。従来からの心外膜あるいは心内膜ＥＣＧ検出並びにペーシング導線を患者と電子的制御体（ＥＣ）２００との間に設けて心臓周期を監視し、血液ポンプ装置の運転を正しく同期させることができる。検出した複合ＱＲＳ信号間の、あるいはペーサーの出力パルス間の時間を使用して、カムとポンピングアームとが心臓周期毎に完全な１サイクルを終了するようにモータの回転速度を制御する。検出された心臓サイクルに関するモータ位置の関連する相は、左心室が膨張し始めるときに検出された心臓サイクルの略半分を過ぎた時に血液チャンバ２０の血液排出相が開始されるように調節される。

【００４３】除細動電極をインプラントシステムの１構成部品として設け、不整頻搏あるいは除細動に際しての治療ショックを送るべくＥＣ２００により制御することができる。インプラントしたバッテリーパックもまたインプラントシステムの一部とすることが可能であり、このバッテリーパックを使用して必要時に再充填するまでに数時間血液ポンプ装置を作動させることができる。通常、インプラントシステムへの電力は、経皮的なエネルギー及びデータ伝達（ＴＥＤＴ）を通して入手することができる。インプラントした、再充填可能なバッテリーパックは、このＴＥＤＴを使用して再充填され得、あるいはＴＥＤＴによる電力供給が行われない場合に、インプラントシステムのための電力を提供することができる。

【００４４】電子制御体はポンピングアーム位置センサ及び任意のＥＣＧ検出/ペーシング用導線を通して受ける信号に基づいてモータ駆動体の運転を管理する。ＣＨＦ患者の心臓補助を最適化するための、レート応答的な心拍数制御及び或はＡＶシーケンス的なペースメーカー形式での制御を提供するための生理学的センサを組み込むことができる。そうした患者の多くは変時性の不全症状に悩まされており、レート応答的な及び或はＡＶペーシングシーケンス的な制御が必要となり得る。ＥＣＧ電線をターミナルブロックを介して電子制御体に結合することができる。ターミナルブロックは除細動治療電線のためのコネクタとしても使用することができる。電子的制御体はＴＥＤＴＳサブシステムによって、あるいはＴＥＤＴＳサブシステムの電力が低下した場合には内部バッテリーパックにより供給される電力により運転される。ＴＥＤＴＳサブシステムは、一方を皮下に、他方を体外に位置付けた２つのコイルと、体外のバッテリーパックと、この体外のバッテリーパック及びコイルを患者の胴部に保持するためのベルトとから構成される。

【００４５】血液ポンプ装置の別の特徴は、機械的エネルギーが血液のポンピングを達成するための血行力学的エネルギーに変換されることである。基本的には、サーボモータの電気エネルギーを血液作業のためのエネルギーに変換するために必要な段階数は一般に最小化するのが望ましい。エネルギー変換の夫々には、変換段階毎の損失を生じる非効率性がある。エネルギー変換段階数を最小化することに加え、各変換段階の効率は最大化されねばならない。

【００４６】図２８のフローダイヤグラムは血液ポンプ装置及び関連するシステム構成部品の各々におけるエネルギー使用及び効率を示すものである。先に議論したように各エネルギー伝達段階にはその段階に関連する効率がある。詳しく説明すると、モータ３２５には内部エレクトロニクス３２０から3.15ワットの電力が供給される。エネルギー変換器を通した後のポンピングアーム３３、血液チャンバ２０そして任意の心臓弁には、循環系３５０に送られるべき1.57ワットの電力が残っているが、これは変換効率が45％であることを意味する。この

値は、競合し得る大抵の装置のそれが10～２５％の範囲であることを考えると血液ポンプ装置のためには高いと言える。変換効率が通常よりも高いのはおそらく、摺動摩擦ではなく回転摩擦によりエネルギー損失を生じる機械的構成部品を使用することによるものであると考えられる。減速装置３３０のエネルギーは主にベアリングでの摩擦による動力散逸により損失を生じる。同様に、カム/ポンピングアーム３３５でもベアリングを通して動力が失われる。更に、エネルギー変換装置の密封シール化が高効率化上の重要な役割を担っている。エネルギー変換装置ハードウェアを患者の体から隔絶することで、人体の塩水環境下には腐食するであろう硬化鋼あるいは“支承用”鋼を使用することができるようになる。こうした材料から作成した構成部品は回転摩擦により引き起こされる損耗に対して代表的には良好な耐久性がある。

【００４７】

【発明の効果】１．関連する電子部品と共に完全にインプラントされ、経皮的な導線に関連する感染の恐れを回避することのできる、十分に小型の血液ポンプ装置に対する需要が満たされる。

２．ポンプの一部或は気密管を使用してポンプに接続した別個のチャンバの何れのチャンバ形態のものであろうとも、たわみ性のための第２のチャンバを必要とすべきではない血液ポンプ装置が提供される。

３．平行な結合通路とは対照的に、大動脈基部から低い充填圧力での血液を受け、受けた血液を、ポンプを駆動して血液を遠方の大動脈に於けるそれよりもずっと高圧化して上行大動脈に戻す血液ポンプ装置が提供される。

【図面の簡単な説明】

【図１】右胸部内に並列接続した血液ポンプ装置を示す透視斜視図である。

【図２】図１に示す位置での、患者の胸郭及び肺間における血液ポンプ装置を示す軸線方向での部分断面図である。

【図３】肺が血液ポンプ装置のためのたわみ性チャンバとして作用する状況を例示する、図２の血液ポンプ装置の軸線方向での部分断面図である。

【図４】図１の血液ポンプ装置の断面平面図である。

【図５】左胸部内に並列接続した血液ポンプ装置を示す透視斜視図である。

【図６】右胸部内に並列接続した血液ポンプ装置の別態様での透視斜視図である。

【図７】左胸部内に直列接続した血液ポンプ装置を示す透視斜視図である。

【図８】右胸部内に直列接続した血液ポンプ装置を示す透視斜視図である。

【図９】動脈血管の組み込み状況を例示する部分斜視図である。

【図１０】動脈血管の組み込み状況を例示する部分斜視図である。

【図１１】動脈血管の組み込み状況を例示する部分斜視図である。

【図１２】動脈血管及び左心室先端部血管の組み込み状況を例示する部分斜視図である。

【図１３】動脈血管及び左心室先端部血管の組み込み状況を例示する部分斜視図である。

【図１４】動脈血管及び左心室先端部血管の組み込み状況を例示する部分斜視図である。

【図１５】クイックコネクタの部分側方断面図である。

【図１６】図１５のクイックコネクタの部分破除した側方断面図である。

【図１７】高分子製の血液チャンバ構成の斜視図である。

【図１８】高分子製の別の血液チャンバ構成の斜視図である。

【図１９】高分子製の別の血液チャンバ構成の斜視図である。

【図２０】血液ポンプ装置の斜視図である。

【図２１】図２０の血液ポンプ装置を線ＸＩＶ－ＸＩＶで切断した断面図である。

【図２２】垂直方向でのピボット運動を例示する図２０の血液ポンプ装置の概略側面図である。

【図２３】高分子製の血液チャンバが図２２に例示されるピボット運動によりポンピングされる状況を例示する部分側面図である。

【図２４】高分子製の血液チャンバが図２２に例示されるピボット運動によりポンピングされる状況を例示する部分側面図である。

【図２５】図２０の血液ポンプ装置を線ＸＶＩＩ－ＸＶＩＩで切断した断面図である。

【図２６】図２５に示す血液ポンプ装置を線ＸＹＩＩＩ－ＸＶＩＩＩで切断した断面図である。

【図２７】図２５に示す血液ポンプ装置のための駆動機構を非同期的に制御する方法を例示するグラフである。

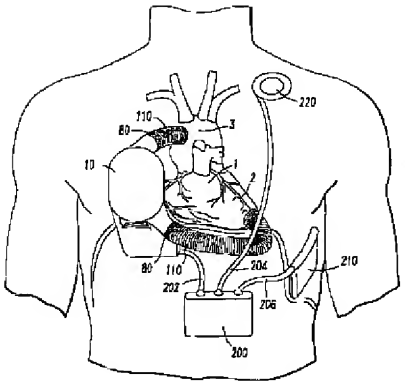
【図２８】図２５に示す駆動機構のための効率ダイヤグラム図である。

【符号の説明】

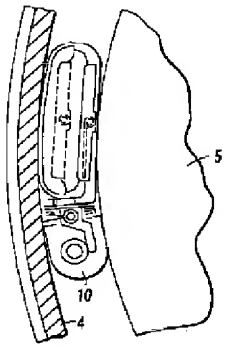
５　肺
１０　血液ポンプ装置
１３　ポンプハウジング
１５　コップ状部分
１８　駆動チャンバ
２０　血液チャンバ
２２　出口導管
２４　入口導管
２８　可動プレート
３３　ポンピングアーム
４３　ベアリング
４５　カム従動節
４７　偏心軸

４８　入力部分
５２　カム
５６　サーボモータ
５８　ステータ部分
６０　ロータ部分
６８　リングギヤ部分
７０　減速装置
８０　クイックコネクタアセンブリ
８２　Ｏ－リング
８４　アクチュエータ隔壁
８６　支持体リング
８８　錠止用スリーブ
９０　錠止用ピン
９２　支持体カラー
９４　圧縮バネ
１００　長孔
１１０　人工血管
２００　電子制御体
２１０　バッテリーパック
２２０　ＴＥＤＴＳ

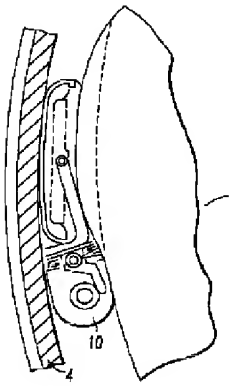
【図１】



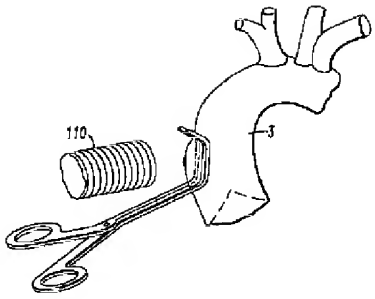
【図２】



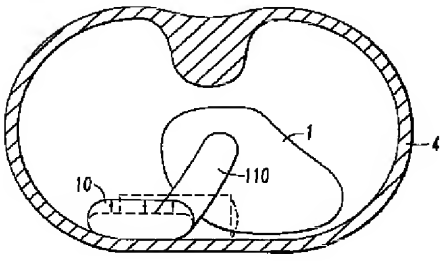
【図３】



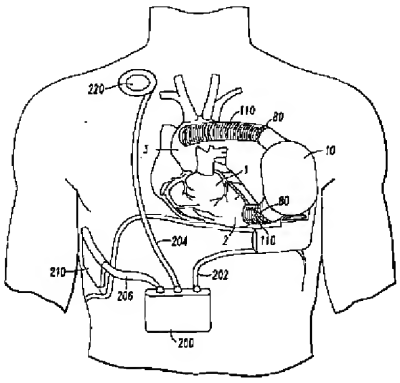
【図９】



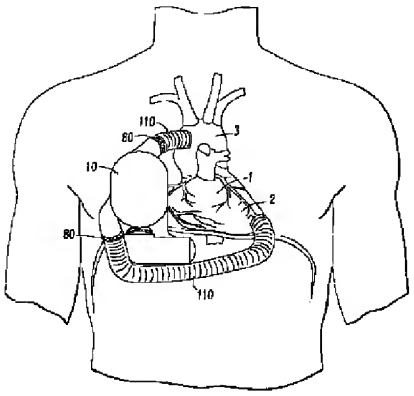
【図４】



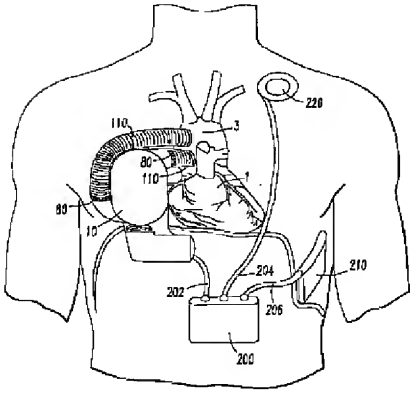
【図５】



【図６】



【図７】



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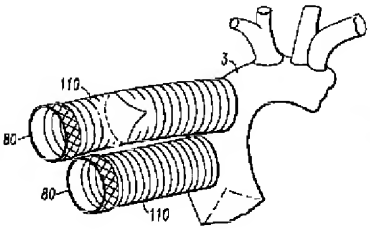

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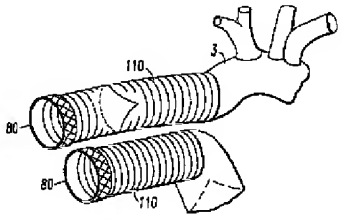

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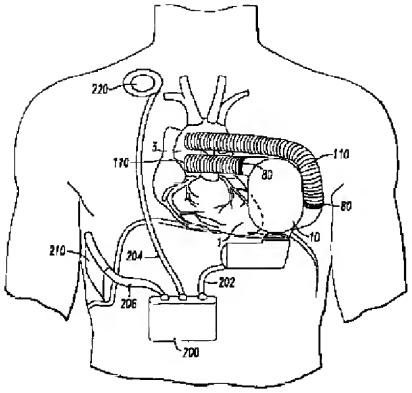

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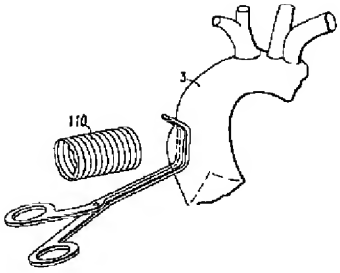

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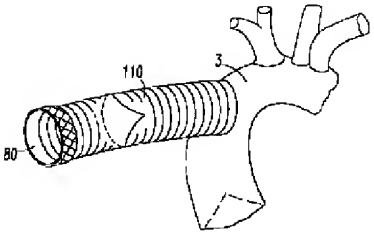

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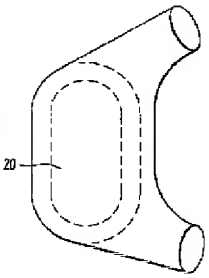

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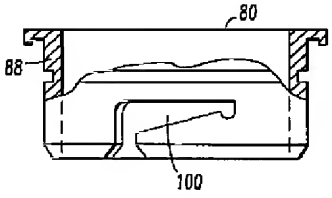

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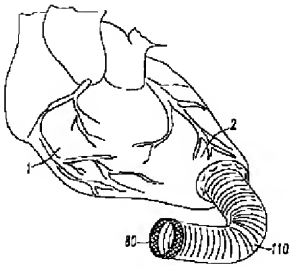

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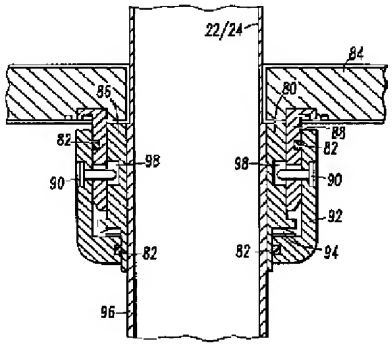

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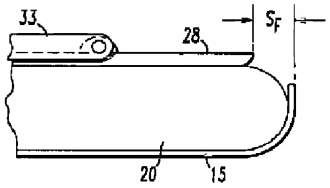

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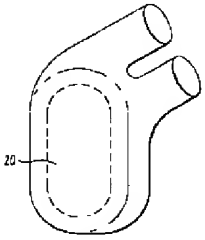

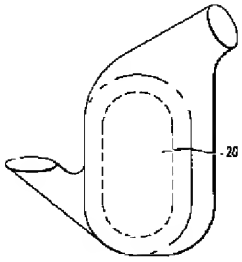

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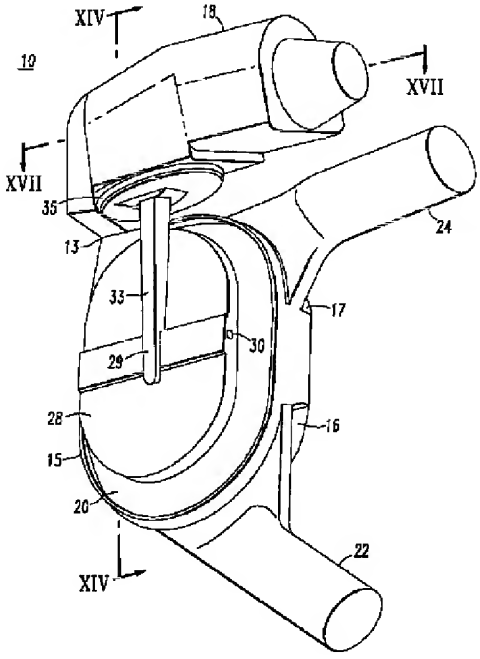

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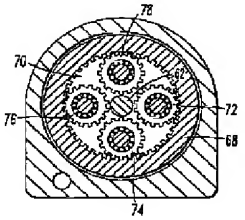

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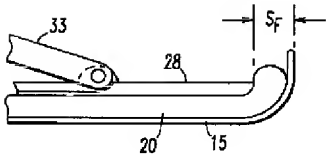

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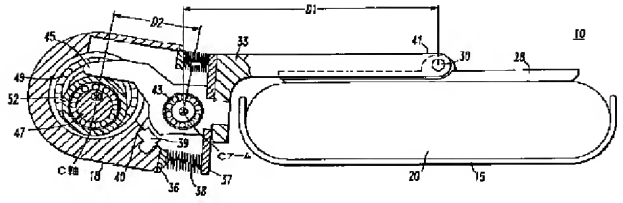

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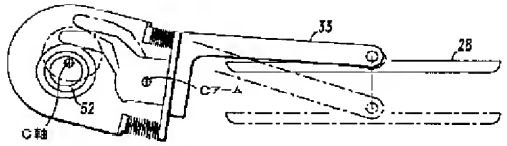

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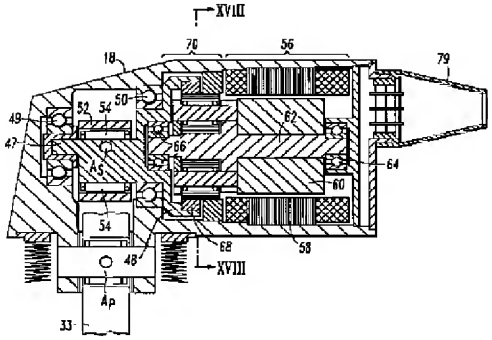

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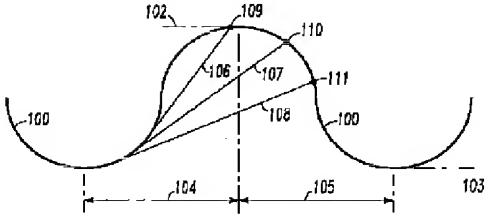

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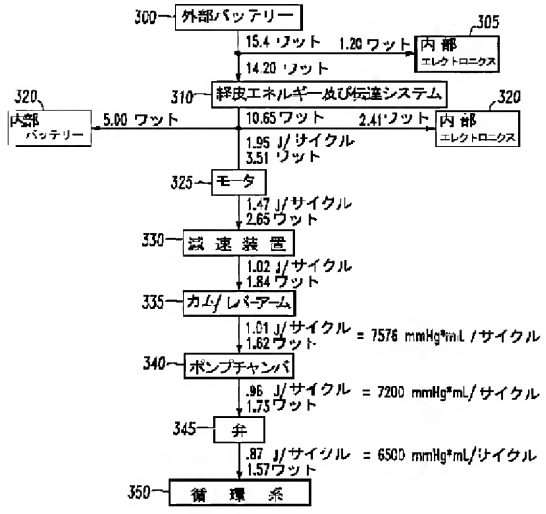

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